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 (CMS-0057-F)

Summary of Final Rule

On January 18, 2024, the Centers for Medicare & Medicaid Services (CMS) placed on public display at the Federal Register a final rule imposing new requirements on Medicare Advantage (MA) organizations, Medicaid and the state Children's Health Insurance Program (CHIP) fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and qualified health plans (QHPs) in the federally-facilitated exchanges (FFEs). These impacted payers will be required to establish or update by 2027 the following Application Programming Interfaces (APIs) that meet specific standards: a Patient Access API updated with prior authorization information, a Provider Access API, a Payer-to-Payer API, and a Prior Authorization API for providers. The policies in this rule are designed to improve the electronic exchange of healthcare data and streamline prior authorization (PA) processes, while continuing to encourage interoperability in the healthcare market. Also in this rule, CMS adds a new measure for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians under the MIPS Promoting Interoperability performance category.

The final rule will be published in the February 8, 2024 issue of the Federal Register.

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I. Background and Summary of Major Provisions

On May 1, 2020, CMS issued the Interoperability and Patient Access final rule[1] (CMS Interoperability and Patient Access final rule), under which CMS required affected payers, including MA organizations, to build and maintain a standards-based Patient Access Application Programming Interface (API).[2] That rule required impacted payers to establish a Patient Access API by 2021, allowing patients, through the health apps of their choice, to easily access their claims and encounter information as well as clinical data, including laboratory results, provider remittances, and patient cost sharing for those claims maintained by the impacted payer. The API must conform with Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR) and meet other specifications. That rule also required the establishment of a Provider Directory API for enrollees as well as payer-to-payer data exchange.

CMS then published a proposed rule[3] on December 18, 2020 (December 2020 CMS Interoperability proposed rule) that built on provisions of the CMS Interoperability and Patient Access final rule and applied to issuers of QHPs in FFEs, Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, and CHIP managed care entities. In that proposed rule, CMS proposed new requirements to improve the electronic exchange of healthcare data and streamline processes related to prior authorization.[4] Also, the Office of the National Coordinator for Health Information Technology (ONC) proposed the adoption of certain specified implementation guides (IGs) needed to support the proposed API policies in that proposed rule. Many comments received in response to the December 2020 CMS Interoperability proposed rule objected that MA organizations were not included among the impacted payers. Other comments expressed concern about the proposed timeframes for implementation as well as the funding necessary to implement the requirements. The proposed rule was never finalized and is withdrawn in this final rule, which contains revised policies that were informed by comments to the December 2020 CMS Interoperability proposed rule.

The revisions in this final rule include applying the requirements to MA organizations and requiring impacted payers to use health information technology (IT) standards at 45 CFR §170.215 that are applicable to each set of requirements for the APIs in this rule—that is, the Patient Access API, the Provider Access API, the Payer-to-Payer API (for when a patient moves

[1] "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, state Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges and Health Care Providers" (85 FR 25510).

[2] HealthIT.gov describes APIs as "tools that support interoperability by allowing different software programs to easily communicate with one other and to share information. If you have ever used a website or mobile app on your computer, smartphone, or tablet to purchase a flight or pay a bill, you have probably used an API."

[3] "Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges; Health Information Technology Standards and Implementation Specifications" (85 FR 82586).

[4] CMS defines prior authorization as the process through which a health care provider, such as an individual clinician, acute care hospital, ambulatory surgical center, or clinic, obtains approval from a payer before providing care. A prior authorization is made up of two parts—a prior authorization request from a provider and a decision by the payer.

between payers, providing up to 5 years of patient data), and the Prior Authorization API.[5] In the proposed version of this rule,[6] CMS had proposed implementation as of 2026 of these APIs containing the required elements and standards. Based on feedback from commenters, CMS finalizes extending these timelines to 2027. CMS believes this approximately 3-year timeline to recruit and train staff, update or build the APIs, and update operational procedures will be sufficient, based on comments and public information from some payers and providers. Other operational provisions will be effective on the date of publication of the final rule, including clarifications to Medicaid beneficiary notice and fair hearing regulations that apply to Medicaid prior authorization decisions and changes to terminology related to the Patient Access API.

Several other requirements for prior authorization processes are finalized for all impacted payers, including that by 2026 they:

- Send information to providers regarding the payer's prior authorization decision and a specific reason for denial when a prior authorization request is denied, regardless of whether the payer receives the prior authorization request through the Prior Authorization API;
- Respond to prior authorization requests within certain timeframes (which would not apply to QHP issuers on the FFEs); and
- Annually report publicly certain metrics about patient data requests made through the Patient Access API.

This rule adds a new "Electronic Prior Authorization" measure for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program and for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS, for the 2027 performance/reporting period. This is designed to promote Prior Authorization API adoption, implementation and use among these participants. In a change from the proposed rule, CMS finalizes that the Electronic Prior Authorization measure will require a MIPS eligible clinician, eligible hospital, or CAH to report a yes/no attestation or (if applicable) an exclusion, rather than a numerator and denominator.

This final rule also specifies an exemption process for state Medicaid and CHIP FFS programs to seek an extension of implementation deadlines, or an exemption from meeting certain requirements, and an exemption process for issuers of QHPs on the FFEs. A new section in this final rule discusses the possibility of states receiving enhanced Federal Financial Participation (FFP)—that is, federal Medicaid/CHIP matching funds—for expenditures related to implementing these requirements.

[5] In the proposed rule, this was referred to as the Prior Authorization Requirements, Documentation, and Decision API, or PARDD API. CMS notes that the name change does not indicate any change to the requirements or standards proposed.

[6] "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," December 13, 2022 (87 FR 76238).

For purposes of this summary, the terms "payer" and "impacted payer" are all-inclusive terms that refer to MA organizations (MAOs), Medicaid and CHIP fee-for-service programs, Medicaid managed care plans (including prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs)), CHIP managed care entities, and QHPs in the FFEs. QHPs in FFEs exclude stand-alone dental plans, and issuers only offering QHPs in the federally-facilitated Small Business Health Options Program Exchange (FF-SHOP) are not subject to this rule. FFEs include Exchanges in states that perform plan management functions; State-based Exchanges on the Federal Platform (SBE-FPs) are not FFEs, even though patients in those states enroll in coverage through HealthCare.gov. Nevertheless, CMS encourages SBE-FPs and state-based exchanges (SBEs) to consider adopting similar requirements for QHPs on their Exchanges.

Other terms used in the rule are clarified. "Patient" is used throughout as an inclusive term, although historically in some programs CMS has referred instead to "consumer," "beneficiary," "enrollee," or "individual" and also uses these terms throughout this rule. The term patient includes a patient's personal representative[7] and could address policies in the rule that require action by a patient. In the context of prior authorization, "items and services" do not include prescription drugs or covered outpatient drugs; however, CMS says it "did not anticipate the overwhelming response to that exclusion under current conditions."[8] In response to other comments, CMS clarifies that supplies, including those dispensed at a pharmacy such as diabetic test strips, and durable medical equipment (DME) that are considered medical benefits and are not prescription drugs are subject to this rule's prior authorization requirements.

The term "API" is described as 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 needing to know the internal workings of A's software, while maintaining data security and patient privacy, if properly implemented.

CMS believes the policies in this rule are aligned with its efforts to advance health equity for all because they may mitigate existing inefficiencies in policies, processes, and technology that affect many patient populations. An individual's ability to select an app of their choice when accessing their health information is cited as an example.

In response to many commenters expressing concern regarding the lack of discussion in the proposed rule on compliance mechanisms, CMS says each of its programs oversees compliance under their respective program authorities, with an array of possible enforcement mechanisms to choose from. The agency then discusses categories of enforcement actions for various payers.

[7] Defined in 45 CFR §164.502(g) and discussed in Office of Civil Rights guidance at https://www.hhs.gov/hipaa/for-professionals/faq/2069/under-hipaa-when-can-a-family-member/index.html

[8] While the claims data addressed in this final rule (for example, in a Patient Access API) also pertain to prescription and other drug claims, this rule's policies related to prior authorization 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 plan. CMS notes there are existing laws and regulations that may apply to prior authorization of drugs for the impacted payers in this rule, which it goes on to describe for each payer (not summarized here). Based on the overwhelming number of comments in support of reconsideration of the policy, however, CMS says it will consider options for future rulemaking to address improvements to the prior authorization processes for drugs.

For MA organizations, for example, CMS may take compliance actions ranging from warning letters to enforcement actions including sanctions, civil money penalties and other measures specified at 42 CFR 422, subpart O. MA enrollees have a right to file a grievance with a plan under the procedures at 42 CFR §422.564, and may also submit complaints to 1-800-MEDICARE or the online complaint system at https://www.medicare.gov/my/medicare-complaint. In addition, the State Health Insurance Assistance Programs (SHIP) are available to help Medicare beneficiaries, including with filing complaints. The agency does a similar walk-through for its oversight of other payers.

II. Provisions of the Rule and Responses to Public Comments

A. Patient Access API

1. Background

The May 2020 Interoperability and Patient Access final rule's provisions requiring a Patient Access API went into effect January 1, 2021. These required affected payers to give patients access to their own health information by sharing, via FHIR APIs, certain information, including patient claims, encounters with capitated providers (encounter data), and a subset of clinical data that patients can access via health apps. Patients tend to receive care from multiple providers, which can lead to fragmented patient health records that can impede care coordination efforts and access to appropriate care.

Specifically, the 2020 Patient Access final rule required certain payers—MAOs, state Medicaid FFS programs, CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs—to implement and maintain APIs that permit enrollees to use health apps to access data specified at 42 CFR §§422.119, 431.60, 457.730, 438.242(b)(5), 457.1233(d), and 45 CFR §156.221, respectively. The Patient Access API must make available, at a minimum, adjudicated claims (including provider remittances and enrollee cost sharing), managed care encounters, and clinical data, including laboratory results, with a date of service on or after January 1, 2016. Payers must make 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.

2. Enhancing the Patient Access API

This final rule adds requirements to the Patient Access API of impacted payers. To support ongoing maintenance of the Patient Access API, CMS is requiring certain specifications and recommending certain IGs, as described in section II.G. Impacted payers are permitted to use updated standards, specifications or IGs not yet adopted in regulation. In addition, as detailed in the subsections below, this rule finalizes requirements that a Patient Access API:

- Includes information on prior authorization requests and decisions,
- Is added as another way that payers must make protected health information (PHI) available to the patient, under the existing privacy rules based on the Health Insurance Portability and Accountability Act (HIPAA), and
- Has usage metrics reported annually to CMS by impacted payers.

Comments/Responses: Multiple commenters expressed general support for the Patient Access API, to promote transparency and improve patient access to health data, and agreeing that the proposed modifications to the Patient Access API would improve patient engagement and shared decision making. Other commenters, however, stated they have not seen significant uptake of health apps since the implementation of the Patient Access API. While they believe in the potential for the Patient Access API, robust utilization has not materialized, possibly because many payers have their own portals or because members prefer to speak with a customer service representative, for instance, on the status of their claims. Some payers noted that while they currently have a low rate of members using apps, they anticipate higher utilization as younger cohorts reach Medicare eligibility.

Several commenters encouraged CMS to consider how to help patients with limited digital or broadband access and recommended CMS require states and other entities to continue to provide written notices instead of relying on electronic communication via the Patient Access API. CMS notes that the rule does not change any applicable obligation for payers to make information available in non-electronic formats. For example, under current regulations, MAOs and Medicaid agencies must give individuals the choice of whether to receive notices electronically or by mail. Under the HIPAA Privacy Rule, covered entities generally must provide individuals access to their PHI in the form and format requested by the individual. Nevertheless, CMS says making digital tools available, such as standardized APIs and health apps that can access them, aligns with how many people interact with other industries today, such as banking and e-commerce. With the Patient Access API, Health Information Exchanges (HIEs) and health apps may be able to gather data from payers, providers, and other sources to create a more comprehensive patient record than could be maintained by the payer alone.

Multiple commenters recommended that CMS ensure the Patient Access API allow caregivers and dependents to have access where patients have provided consent. CMS notes that, under the HIPAA Privacy Rule (45 CFR §164.502(g)), a personal representative is a person authorized under state or other applicable law to act on behalf of the individual in making health care related decisions (such as a parent, guardian, or person with a medical power of attorney). With limited exceptions, a personal representative is treated as the individual for purposes of the HIPAA Privacy Rule. Similarly, existing Patient Access API policies already explicitly apply to patients' personal representatives.[9]

a. Prior Authorization Information

CMS finalizes its proposal to require impacted payers to provide patients, through the Patient Access API, with access to information about prior authorization requests and decisions made for their care and coverage. The rule specifies the information about prior authorizations that must be available through the Patient Access API. This includes all prior authorization requests and decisions for items and services (excluding drugs) for which the payer has data, and the status of that decision (e.g., pending, active, denied). (Section II.D. summarizes provisions to make the prior authorization process less burdensome for providers and payers.)

[9] 42 CFR §422.119(a) and (b)(1), 42 CFR §431.60(a) and (b), 42 CFR §457.730(a) and (b), and 45 CFR §156.221(a) and (b).

Via the Patient Access API, impacted payers must make prior authorization information available to patients not later than 1 business day after the payer receives the prior authorization request or another type of status change occurs for the prior authorization (for example, approval or denial of a prior authorization request). Regardless of the impacted payer's terminology, the requirement to update the information available to the patient must generally apply to any meaningful change to the payer's record of the prior authorization request or decision. The required information includes the following:

- The prior authorization status,[10]
- Date the prior authorization was approved or denied,
- If denied, the specific reason for denial (as described in greater detail in section II.D.),
- Date or circumstance under which the authorization ends, and
- Items and services approved.[11]

Impacted payers will also be required to include this prior authorization information via the Provider Access API (section II.B.) and the Payer-to-Payer API (section II.C.) so that it is available to all relevant parties.

Comments/Responses: A significant majority of commenters expressed support for CMS' proposal to include prior authorization information in the Patient Access API, to empower patients in their care, reduce the burden of repeated inquiries to payers, and facilitate faster decisions by allowing patients to help providers submit the necessary documentation. Multiple commenters highlighted current challenges for patients to access their prior authorization information.

Other commenters expressed concerns that many patients do not have an overall understanding of the prior authorization process and that giving them access to prior authorization information would add to existing confusion. CMS says that while not all patients will want to access their prior authorization data or fully understand the information, this is insufficient justification for not making those data available to patients who want that access and insight into their care. While the policies in this section pertain only to information available through the Patient Access API, CMS urges payers to make prior authorization information available to patients regardless of how they inquire—whether via online patient portal, phone call, or e-mail.

To alleviate administrative burden, some commenters recommended that prior authorization information be included in the Patient Access API only if it came from requests submitted via a Prior Authorization API. While CMS acknowledges that an additional step will be required to convert non-electronic requests (e.g., phone or fax), payers have to do this regardless of the Patient Access API. Since the same prior authorization data are generally required for the Provider Access and Payer-to-Payer APIs, as well, this creates economies of scale as the burden of data translation will only occur once. In addition, CMS believes patients should have access to their prior authorization information, regardless of the process between their provider and payer.

[10] In the preamble, CMS lists what it considers as five basic statuses: pending, active, denied, expired, or authorization not required. However, this list does not appear in regulation text.

[11] In this final rule, based on feedback from numerous commenters, CMS dropped from the list requiring payers to share the quantity of items or services used under a prior authorization as well as unstructured documentation related to a prior authorization.

In response to a request for clarification, CMS states that the required information in the Patient Access API does not need to be "pushed" to a patient app, but should be available for query if a patient chooses to use their app to retrieve their information. The agency also notes that impacted payers are not required to accept a prior authorization request or supporting documentation directly from patients, for fear this would create confusion about whether the provider or patient is ultimately responsible for the submission of prior authorization requests and documentation. CMS says providers are in the best position to understand the clinical requirements to obtain prior authorization and are responsible for using their clinical judgment to decide on the best course of treatment.

Regarding the five basic prior authorization statuses described in the preamble (pending, active, denied, expired, and authorization not required), some commenters recommended additional statuses and others recommended fewer. Definitions of these terms were also requested, but CMS opted not to provide any, stating that payers use a variety of processes and that the agency does not intend to prescribe exactly when a particular status must be used, but that such status should be clear and understandable to patients and providers. CMS welcomes payers to use other statuses that provide additional information or are more specific to their process.

Commenters suggested that the Patient Access API include prior authorization information on:

- Whether the requesting provider is in-network or out-of-network, and
- The names and contact information for the in-network provider who can furnish the appropriate service within the time and distance standards required by law.

CMS notes that the rule makes no distinction between in-network and out-of-network providers regarding the prior authorization information available through the Patient Access API; the required information must be shared with patients regardless of the requesting provider's network status. CMS does not believe that the appropriate place for the provider's network status is with prior authorization information. The agency further notes that FHIR API technical specifications and IGs for the Patient Access API are not built to include information on a provider's network status. Rather, this information is required by MA organizations, state Medicaid and CHIP FFS programs, Medicaid and CHIP managed care plans through a Provider Directory API, per the 2020 CMS Interoperability and Patient Access final rule (85 FR 25563). CMS encourages developers to integrate information from payers' Provider Directory APIs within their apps network for easy patient access.

As previously mentioned, CMS finalizes requiring payers to make available via the Patient Access API information about prior authorization requests and decisions to patients no later than 1 business day after the payer receives the prior authorization request or there is another status change. This provides patients with needed timely access to the information to understand prior authorization processes and their available care options. As described in section II.D., much of the same information is required in the Prior Authorization API and, according to CMS, because impacted payers would be required to exchange the information electronically, it is reasonable for payers to share the information in the Patient Access API within one business day. Many commenters voiced support for this provision, but others (specifically payers) said this timeframe may not be operationally feasible. Many suggested moving to a 2 business day response requirement. Rather than change this requirement regarding the timing, CMS is altering other proposed policies to enable compliance, such as dropping the requirement to include

unstructured prior authorization documentation in the Patient Access API and extending the compliance date by 1 year, to 2027.[12]

A majority of commenters supported CMS' proposal to require prior authorization information to be available via the Patient Access API for as long as the authorization is active[13] and for 1 year after the last status change. Some commenters suggested various longer alternatives, but CMS finalizes this policy as proposed. As a reminder, CMS' 2020 Interoperability and Patient Access final rule (as modified by this final rule) requires payers to make available through the Patient Access API any claims and encounter data, and all data classes and data elements included in a content standard at 45 CFR §170.213 (USCDI), which includes clinical data, maintained by the impacted payer with a date of service on or after January 1, 2016.

b. Interaction with HIPAA Right of Access Provisions

Under the HIPAA Privacy Rule, patients generally have a right of access to obtain a copy of PHI about themselves in a designated record set (45 CFR §164.524). This rule finalizes requiring payers to make that information available through a standards-based and interoperable FHIR API, the Patient Access API. This will enable patients more access to their data through health apps, as they become more common, and reduce instances of an individual requesting electronic PHI (ePHI) in a format that is not readily producible.

CMS reiterates the right that individuals have under the HIPAA Privacy Rule to request access to PHI in the form and format they request. This includes where the requested mode of transfer or transmission is not secure (as along as the information is "readily producible" in such manner, the covered entity is capable of transmitting the PHI accordingly, and that transmission would not present an unacceptable security risk to the PHI on the covered entity's own systems). Thus, disagreement with the individual about the worthiness of a health app as a recipient of PHI, including concerns about what the app might do with the PHI, would not be acceptable reasons to deny an individual's request.[14] Covered entities and business associates would be free to offer advice on the potential risks with requested data transfers to an app or entity not covered by HIPAA, but such efforts generally must stop at education or advice related to a specific app. The covered entity is not liable for what happens to the PHI once the designated third party receives the information as directed by the individual.

CMS' policies address how a payer must make patients' data available but does not have the authority to regulate the health apps that individuals use or what those apps do with PHI. However, other federal laws may apply, such as the Federal Trade Commission (FTC) Act—for example, if an app discloses an individual's health information in a manner inconsistent with the app's privacy policy. For more information about what laws may apply to health apps, CMS

[12] In this summary, references to a 2027 compliance date for impacted payers means, specifically, by January 1, 2027 for MAOs 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.

[13] Even if they have been in that status for more than 1 year.

[14] In the CMS Interoperability and Patient Access final rule, CMS established that the only reason payers could deny API access to a patient's preferred health app is if it would present an unacceptable level of risk to the security of PHI on the payer's own system (e.g., 85 FR 25558).

refers readers to https://www.ftc.gov/business-guidance/resources/mobile-health-apps-interactive-tool. The FTC also enforces the FTC Health Breach Notification Rule, which applies to most health apps and similar technologies that are not covered entities or business associates under HIPAA. The FTC brought its first enforcement actions under this rule in 2023.[15]

c. Patient Access API Metrics

CMS finalizes requiring payers to report metrics (aggregated and de-identified) to CMS on an annual basis about how patients use the Patient Access API, to help CMS evaluate if:

- Patients are obtaining access to their health information;
- Payers are providing required information in a transparent, timely way; and
- CMS should provide targeted support or guidance to payers.

The following information will be required:

- The 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, as an indication of repeated access.

As proposed, CMS finalizes that payers must report metrics from the previous calendar year to CMS by March 31 of each year, beginning with reporting calendar year (CY) 2025 data by March 31, 2026. The agency says it may publicly report these data in an aggregated and de-identified format, but will not include names of specific state agencies, plans, or issuers unless and until proposed through future rulemaking.

Comments/Responses: Most commenters supported the proposed metrics. In response to comments that these metrics will reflect factors beyond a payer's control, CMS notes their intent is not to evaluate or compare payers but to help the agency understand how patients are using apps and the effectiveness of the Patient Access API policies. If patients prefer to use online portals, rather than apps, that could inform future rulemaking.

CMS proposed that the information would be reported at the following levels:

- MAOs at the organization level,
- State Medicaid and CHIP FFS programs at the state level,
- Medicaid managed care plans at the state level,
- CHIP managed care entities at the state level, and
- QHP issuers on the FFEs at the issuer level.

While many commenters supported the proposal, multiple commenters recommended a more granular metric reporting level for MAOs. Commenters' recommendations covered a range of possible levels of aggregation. In response to comments, CMS revises its proposal so that MAOs

[15] *U.S. v. Easy Healthcare Corp.*, Case No. 1:23-cv-3107 (N.D. Ill. 2023), https://www.ftc.gov/legal-library/browse/cases-proceedings/202-3186-easy-healthcare-corporation-us-v; *U.S. v. GoodRx Holdings, Inc.*, Case No. 23-cv-460 (N.D. Cal. 2023), https://www.ftc.gov/legal-library/browse/cases-proceedings/2023090-goodrxholdings-inc.

must report at the contract level, rather than the organization level, consistent with other reporting required of MAOs.

A few commenters requested clarification on the level at which integrated care plans for dually eligible individuals should report Patient Access API metrics. Such plans generally combine a dual eligible special needs plan (D-SNP), which include fully integrated dual eligible special needs plans (FIDE SNPs) and highly integrated dual eligible special needs plans (HIDE SNPs). Both types of plans are defined as an MA plan and a Medicaid managed care plan offered by the same parent organization (42 CFR 422.2). Thus, as finalized, an MAO will report information about Patient Access API usage by its D-SNP enrollees to CMS at the MAO's contract level, and the affiliated Medicaid managed care plan will report at the plan level.

d. Patient Access API Amendments

Two minor terminology changes were finalized as proposed for the Patient Access API regulatory text applicable to each of the impacted payers. First, the existing requirement that APIs make available "clinical data, including laboratory results" is replaced by "all data classes and data elements included in a content standard at 45 CFR 170.213" which is the USCDI version 1 and includes lab results, immunizations, procedures, and assessment and plan of treatment. Second, in the text addressing denial or discontinuation of access to the API, the term "parties" replaces "enrollees" and "beneficiaries" as other parties may be accessing the APIs, such as providers and payers. All commenters supported CMS' effort to keep the Patient Access API required data aligned with ONC's standards. These two provisions go into effect on the effective date of the final rule, unlike most of this rule's changes.

e. Specific CHIP-related Regulatory Framework

CMS finalizes its proposal to align separate CHIP managed care API requirements with Medicaid managed care API requirements (rather than CHIP FFS API requirements). Medicaid-expansion CHIP programs (that is, where a state uses its Medicaid program to cover CHIP-eligible children) would be subject to Medicaid rather than separate CHIP policies in this rule. See section II.E. for discussion of implementation for Medicaid-expansion CHIP programs.

3. Other Requests for Comment

CMS lists areas where it had requested comment in the proposed rule but had not offered proposals—for example, on how could and should CMS apply these requirements to Medicare FFS and its existing prior authorization requirements and standards, and what policy levers it might have to create norms or best practices for privacy policies by health app developers. The agency did not describe those comments and provided no response except expressing appreciation to submitters.

4. Final Action and Statutory Authorities for the Patient Access API Proposals

CMS again summarizes the finalized provisions of the Patient Access API, along with the rationale for the policies and the underlying statutory authority for each of the impacted payer types. The following policies were modified from those proposed:

- Impacted payers must make information about prior authorization requests and decisions available via the Patient Access API beginning 2027, rather than in 2026.
- Impacted payers are not required to share the quantity of items or services used under a prior authorization via the Patient Access API.
- Impacted payers are not required to share unstructured documentation related to prior authorizations via the Patient Access API.
- MA organizations must report Patient Access API metrics at the contract level rather than at the proposed organizational level.

B. Provider Access API

1. Background and Summary

In the May 2020 Interoperability and Patient Access final rule, policies were implemented (effective January 1, 2021) so the Patient Access API could allow patients to access their health information through an app and potentially share that information with their provider during an appointment. In the proposed version of that rule, CMS had sought comment on the feasibility of implementing and maintaining a FHIR API for data exchange between payers and providers and received comments strongly supportive of requiring data availability through a Provider Access API, including information about prior authorization decisions. More data could be available to help providers manage a patient's care, and providers could reduce or eliminate duplicate tests. Payers could benefit by seeing fewer duplicate requests for services, fewer appeals and possibly lower costs.

This final rule requires impacted payers (not including Medicare FFS) to implement by 2027 and maintain a Provider Access API—that is, a FHIR API to exchange data with providers who have (1) a contractual relationship with the payer and (2) a treatment relationship with the patient. CMS is also finalizing a patient opt-out (rather than an opt-in) policy, requiring payers to allow patients to opt out of the Provider Access API.

Although these policies do not pertain to Medicare FFS, CMS notes that its Data at the Point of Care (DPC) project is currently piloting an API that makes Medicare FFS claims and Part D data available to certain providers. Because provider remittances and patient cost-sharing information are not proprietary in Medicare FFS, those data are shared in the DPC pilot, which is not required of impacted payers in this rule. Because the DPC API enables provider access to patient data and involves processes like authenticating the provider and verifying a patient treatment relationship with an attribution process, CMS says the information gained from the DPC pilot will be useful to impacted payers.

2. Requirements for Payers: Provider Access API for Individual Patient Information

CMS believes it would be valuable for providers to have access to the same data available through the Patient Access API (except for provider remittances and enrollee cost-sharing information) through a FHIR API, citing research that patients achieve better outcomes when their record is more complete and there are more data available to the provider at the point of care. It can also reduce burden on patients to recall information regarding prior care.

CMS finalizes requiring that impacted payers implement and maintain a Provider Access API to enable the information of current patients to be exchanged from payers to providers that are in that payer's network,[16] at the provider's request. Both the Provider Access API and the Patient Access API must use FHIR-based exchange of claims and encounter data, as well as all data classes and data elements included in the content standard at 45 CFR §170.213. Both also require payers to share similar information on prior authorization requests and decisions for items and services (excluding drugs), as described in section II.A.2.a. above.[17]

To help providers gain efficient access to more comprehensive data on their patients, CMS finalizes requiring impacted payers to make available through the Provider Access API any of the applicable patient data with a date of service on or after January 1, 2016, consistent with the Patient Access API as finalized in 2020. Thus, payers should already be maintaining and making available data from this timeframe via a FHIR API.

CMS describes a few notable differences between the Patient Access API and the Provider Access API. For the Patient Access API, patients are requesting their own information through a health app for their own use. For the Provider Access API, providers will receive access to the patient's information securely through their EHR or practice management system for treatment purposes (not through their own health app). Unlike the Patient Access API, the Provider Access API will not include provider remittances and enrollee cost sharing information, since those are considered by many payers to be proprietary and would have limited benefit for treatment or care coordination.

Linking to the Patient Access API technical requirements, the Provider Access API will require adherence to the same technical standards, API documentation requirements, and standards for denial or discontinuation of access to the API. Additional details on applicable standards for the Provider Access API are described in section II.G.

Unlike the 2020 proposed rule, this rule does not require payers to provide patient data to a provider that does not have a provider agreement or is not enrolled (in the case of Medicaid and CHIP FFS programs) with the payer holding the patient's data—even though it may be permissible or even required by other law or regulation. CMS says it will continue to consider a requirement to share patient data with out-of-network providers for future rulemaking. Nevertheless, CMS encourages payers to share information via API with out-of-network or unenrolled providers who have a verified treatment relationship with the patient, to the extent permitted by law.

CMS emphasizes that all data shared and received via this data exchange would still have to be handled in a way that is consistent with all current and applicable laws and regulations, including HIPAA, and these policies are not intended to modify those requirements. However, HIPAA

[16] That is, any provider or healthcare facility that is part of a specific health plan's network of providers with which it has a contract. For Medicaid and CHIP FFS programs, this means any providers or facilities enrolled with the state as Medicaid or CHIP providers.

[17] As with the Patient Access API policies, CMS is finalizing a modification to not require payers to share the quantity of items or services used under a prior authorization or unstructured documentation related to a prior authorization.

transaction standards would not be applicable, since those only apply for exchanges requesting or issuing a payment.

The security framework of the API, as required by reference to standards in 45 CFR §170.215, allows payers to verify the requesting provider's identity by using required authorization and authentication protocols. In addition, the payer will be required to share the specified data only if it can also attribute the patient to the provider using an attribution process described below.

Medicaid and CHIP plans and entities that are Non-Emergency Medical Transportation (NEMT) Prepaid Ambulatory Health Plans (PAHPs) are exempt from the requirement to establish a Provider Access API, due to the unique nature and limited scope of the services these plans provide. CMS does not believe that providers have a routine need for NEMT data. (These plans are also exempt from some managed care plan requirements in 42 CFR Part 438, but they must comply with the Patient Access API requirement.)

CMS finalizes its proposal that a payer must make the data available through the Provider Access API no later than 1 business day *after* receiving a request from the provider, if all the following conditions are met:

- The payer authenticates the identity of the provider that requests access and attributes the patient to the provider under the required attribution process;
- The patient does not opt out of the Provider Access API; and
- Disclosure of the data is not prohibited by law.[18]

Comments/Responses: Multiple commenters supported CMS' proposal to require impacted payers to develop and maintain a Provider Access API, which they believe will give providers invaluable insights into patient care and which could lead to better quality care, reduce duplicate services, and streamline provider workflows.

Some commenters supported the proposed compliance date of 2026, others recommended earlier compliance dates, and others called for delaying to 2027. CMS finalizes delaying compliance dates for the Provider Access API to 2027 while also encouraging payers to meet the requirements of this rule as soon as possible to benefit their patients and providers.

Multiple commenters requested clarification on the definition of "providers" that are eligible to use the Provider Access API. CMS says that providers who should have access to a patient's data are those—whether they are an individual, a facility, or a group of providers who have come together as an Accountable Care Organization (ACO)—who are appropriately licensed, provide items or services eligible for coverage by the payer, and are enrolled with the payer or in the payer's provider network. If a clinical laboratory or other entity such as an ACO meet these criteria, it would indeed be a provider who could use the Provider Access API to access patient data, assuming all other criteria outlined in this final rule are met. This includes multiple providers in the same practice if the practice is enrolled with a plan under a Type 2 NPI (that is, an organization's NPI) or if those providers are part of an ACO that is requesting data on a

[18] CMS notes that its policies in this regulation will not alter any obligation for providers or payers to comply with applicable law, including obligations for HIPAA covered entities to follow the HIPAA Rules.

provider's behalf, because all the providers in such organizations would be part of the payer's network.

Commenters recommended that CMS seek to understand the current state of health IT and the needs of end users before mandating Provider Access API implementation. One said that the health IT infrastructure across the industry is not ready to support the APIs. Another noted that when they surveyed their payer members on the Provider Access API implementation, 64.3 percent of payers responded it would be "very difficult or difficult" to implement. CMS disagrees with the commenters' assessment that existing health IT infrastructure is not ready to support the Provider Access API, since they are currently required to maintain a Patient Access API that enables the exchange of the same data as required via the Provider Access API. CMS notes that, as of October 2018, eligible professionals and hospitals collectively received over $38 billion in incentives to adopt, implement, upgrade (AIU), and demonstrate meaningful use of certified EHR technology (CEHRT) through the Medicare and Medicaid Promoting Interoperability Programs (formerly the Medicare and Medicaid EHR Incentive Programs). As of 2021, 78 percent of office-based physicians and 96 percent of non-federal acute care hospitals had adopted CEHRT, which now incorporates functionality for standards-based FHIR APIs.

Multiple commenters agreed with CMS' proposal to not require payers to make available provider remittances and patient cost-sharing information, as it would likely only have a limited beneficial impact on care and could cause confusion. A commenter stated the cost-related data currently available via from the Patient Access API are not very clear, which could lead to different implementations and increased ambiguity when implementing the Provider Access API. As previously stated, CMS agrees with commenters that including this information in the Provider Access API would have limited benefit for treatment or care coordination; regardless of whether provider remittance information or cost-sharing information are truly confidential or proprietary information protected from disclosure under federal law, excluding such data from the Provider Access API is appropriate. However, this rule does not prohibit payers from providing that information if a payer believes it would be beneficial or reduce burden.

Many other commenters urged CMS to reconsider excluding cost-sharing information from the Provider Access API because providers with access to this information can make more informed decisions regarding patient care by incorporating cost into treatment plans and help maintain a good provider-patient relationship. Many possible technical solutions were offered by commenters. While CMS expressed appreciation for the suggestions and acknowledged that such information could be useful to providers for helping patients understand their costs, the primary purpose of the Provider Access API pertains to health care treatment, not cost. Moreover, in-network and enrolled providers should generally be aware of the costs of various treatments under their contracts.

Some commenters requested clarification regarding the policy that the data available through the Provider Access API are data with a date of service on or after January 1, 2016 maintained by the payer. CMS says that by "maintained," it means data that are maintained as part of normal operations, as is existing policy for the Patient Access API under the 2020 CMS Interoperability and Patient Access final rule. The agency did not propose to change that date but also recognizes the volume of data dating back to January 1, 2016 could be a substantial amount and potentially

more than some providers will need. While CMS is finalizing the proposal to require impacted payers to make available via Provider Access API any of the applicable patient data with a date of service on or after January 1, 2016 that the payer maintains, it says it will closely monitor whether this timeframe is appropriate, to inform possible future rulemaking.

Multiple commenters supported CMS' proposed requirement to leverage the Bulk Data Access IG for the Provider Access API, so that if a provider has a panel of patients associated with a single payer, the payer can share those data asynchronously in one transaction. As discussed in section II.G., CMS is finalizing the proposal for impacted payers to use the Bulk Data Access IG at 45 CFR §170.215(d)(1) to support implementation of the Provider Access API. Other commenters recommended CMS limit the API to only individual data requests and not require FHIR Bulk Data Access, as it has not been adequately implemented and noting a number of technical concerns. CMS responds that although it is requiring impacted payers to support FHIR Bulk Data Access at 45 CFR 170.215(d)(1) under this final rule, this requirement does not obligate them to use it for every data exchange if it is not feasible.

Multiple commenters recommended promoting payer-to-provider information exchange through the Trusted Exchange Framework and Common Agreement (TEFCA) rather than a requirement to implement FHIR APIs. CMS says it will continue to work closely with ONC on policies as they relate to TEFCA and how it can align policies that require API development or enhancement for payers with TEFCA to ensure Participants and Subparticipants can utilize this network infrastructure to meet these API requirements.

3. Additional Requirements for the Provider Access API

a. Attribution

Patient attribution is a method of identifying a patient-provider treatment relationship. In this context, attribution ensures that patient health data is shared only with appropriate providers. As finalized, payers will be required to establish and maintain an attribution process—to associate patients with their in-network or enrolled providers—to enable payer-to-provider data exchange via the Provider Access API.

CMS encourages payers to use processes they may already have to attribute patients to their in-network providers for various other purposes, including through health information exchanges (HIEs) and ACOs, but notes it did not propose a specific attribution method. The agency says its goal is to allow payers to develop the least burdensome approach to attribution. As a potential model, CMS points to the attribution process in DPC, which is the Medicare FFS version of the Provider Access API and requires HIPAA-covered entities or their business associates to agree to certain terms of service before data can be sent to them. The current terms of service require organizations to maintain a list of patients being treated at their facilities, along with other requirements. In the proposed rule, CMS sought comment on other examples of how payers can attribute patients to their enrolled or in-network providers, especially for a new patient-provider treatment relationship, noting that payers could accept proof of an upcoming appointment to verify the provider-patient treatment relationship.

Comments/Responses: Commenters asked a number of questions about the providers' role in attribution—for example:

- Whether the provider or the payer must maintain records of the attribution.
- How to account for ACO or value-based care (VBC) coverage models that permit patients to choose a provider.
- Whether VBC attribution is adequate when it is generally geared toward identifying a singular accountable primary care physician.
- Whether multiple providers could be attributed to the same patient at a time.
- Whether the rendering provider is the provider who has a treatment relationship with the patient, or if the billing provider could also be attributed to the patient to request data using the Provider Access API.

CMS says this final rule imposes requirements on impacted payers, not providers. Thus, payers are responsible for maintaining attribution records and ensuring that only in-network or enrolled providers who have a treatment relationship with the patient (or should they choose, out-of-network or unenrolled providers to whom the impacted payer has attributed a patient) have access to patient data. However, the process of attribution inherently requires provider participation in some instances. For example, when a patient has their first visit with a particular provider, the payer cannot be expected to have that information without some provider input. If payers involve patients in their attribution processes, such involvement should not be onerous for the patient.

While CMS is not being prescriptive in how payers should design their attribution processes, the agency cautions that payers should not set overly onerous criteria for providers to prove their treatment relationship with a patient. Payers can attribute most patients to providers via claims, which should not require providers to operate significantly outside their normal workflows to demonstrate a care relationship with a patient. Patients can (and in many cases should) be attributed to multiple providers who would be able to request access to the patient's data.

b. Opt Out

CMS finalizes its proposal without modification that all impacted payers must have a process to allow patients or their personal representatives to opt *out* of having the patients' data available through the Provider Access API.[19] CMS says defaulting to share data with providers, unless a patient opts out, appropriately balances the benefits of data sharing with the right of patients to control their health information. In response to the 2020 proposed rule as well as the proposed version of this rule, commenters overwhelmingly supported an opt-out model, citing clinical and operational hurdles with an opt-in approach.

An opt-out by the patient would apply to all providers in the payer's network. However, CMS encouraged payers to allow more granular controls over the opt-out process—for example, so patients can opt out of making data available to an individual provider.

[19] Opt-out policies allow patients' information to be shared unless they affirmatively revoke that permission. Opt-in policies require affirmative permission from a patient before their data can be shared. Payers must have an opt-*in* process for patients in the Payer-to-Payer API policies finalized in section II.C.

As with attribution, CMS is not prescriptive in how the opt-out process is implemented. However, CMS anticipates payers would make this process available by mobile smart device, website, or apps, while also allowing mail, fax, or telephonic alternatives. Payers would have to make this opt-out process available (and give all currently enrolled patients or their personal representatives a chance to opt out) before the first date on which patient information is made available through the Provider Access API. Payers must also have a process for patients to opt back in.

CMS believes that an opt-out model could address equity issues by ensuring that patients from lower socioeconomic and minority groups, who are more likely to have limited health literacy, can benefit from the improved care that the Provider Access API can facilitate. The agency believes that data sharing as the default option for all patients enhances both personal and organizational health literacy, while protecting patients' choice to limit data sharing.

Comments/Responses: Multiple commenters expressed support for the opt-out approach. Although others raised concerns, CMS says they did not specifically recommend a different approach; on the other hand, CMS also notes that multiple commenters recommended an opt-in approach.

Multiple commenters said that a process requiring patient permission for data sharing via the Provider Access API is not necessary because the HIPAA Privacy Rule permits PHI disclosure without patient permission under certain circumstances—for example, if the PHI disclosed via the Provider Access API falls within the scope of HIPAA treatment, payment, and operations (TPO) disclosures. These commenters recommended that CMS limit the data shared via the Provider Access API to the scope of permitted TPO disclosures, thus eliminating the need for an opt-out process, which could be confusing and cumbersome to patients. Another commenter recommended that CMS make it clear that payers may still share certain patient health information with providers if it falls under the scope of a TPO disclosure, even when a patient opts out.

While acknowledging that existing HIPAA Privacy Rule provisions permit PHI disclosure without an individual's authorization under certain circumstances (e.g., the TPO exception), impacted payers would be required to disclose any PHI specified within the content standards for the Provider Access API.[20] In addition, if a disclosure to a provider is permissible under the TPO exception, even if the patient opted out of the Provider Access API, it would not prohibit a payer from using the Provider Access API to make that disclosure. CMS says payers should make these nuances clear to patients in their required educational resources, so that patients understand that their PHI may still be shared in some instances, even if they or their personal representative opts out of the Provider Access API.

[20] Such disclosure would be permitted under the HIPAA Privacy Rule as "uses or disclosures that are required by law" (45 CFR §164.512(a)), rather than as a permitted TPO disclosure (45 CFR §164.506). As a result, per 45 CFR §164.502(b)(2)(v)), such disclosures are also not subject to HIPAA's "minimum necessary" standard; all content required by the Provider Access API policy may be disclosed. Thus, the opt-out opportunity pertains to this *additional* data.

While multiple commenters suggested that CMS require a standardized opt-out process, CMS says that could impose unnecessary burden on payers. Rather, CMS will continue to monitor implementation of the Provider Access API opt-out requirement to ensure payers' processes are easy and intuitive for patients.

c. Patient Educational Resources Regarding the Provider Access API

CMS finalizes requiring payers to do the following:

- Provide information to patients about
    - The benefits to the patient of API data exchange,
    - Their opt-out rights, and
    - Instructions on how to opt out (and to opt back in),
- Provide the information in easy-to-understand language, at the start of coverage and annually, and
- Make this information easily accessible at all time on payers' public websites.

In a modification from the proposed version, CMS requires that impacted payers provide this information to patients no later than one week after the start of coverage, rather than at enrollment. Another modification is that CMS requires the educational information to be in plain language, rather than the proposed "non-technical, simple, and in easy-to-understand language." This change is intended to encourage impacted payers to follow the federal government's plain language guidelines.[21]

Based on feedback, CMS intends to develop additional outlines or templates for patient education resources.

d. Provider Resources Regarding the Provider Access API

CMS finalizes its proposal that payers must provide educational resources for providers on how to request access to patient data though the Provider Access API and on the payer's attribution process. The information must be provided on the payer's website and other appropriate provider communications (for example, annual contract updates).

In a modification from the proposed version, CMS also requires the provider resources to be in plain language, rather than the proposed "non-technical, simple, and in easy-to-understand language," consistent with the change to the patient education resources policy, described above.

Based on comments received, CMS intends to provide general guidelines to impacted payers about what is required to be disseminated to providers, which may include information on potential best practices. However, unlike the patient-facing educational resources, the agency expects that provider resources could vary significantly between payers, since payers will have different processes to allow providers to request data via the Provider Access API and policies for patient attribution to explain to their providers. Therefore, there is less benefit to standardized templates or content for these resources.

[21] https://www.plainlanguage.gov/guidelines/

4. Final Action and Statutory Authorities for Provider Access API

CMS again summarizes the finalized requirements for the Provider Access API, along with the rationale for the policies and the underlying statutory authority for each of the impacted payer types. The following policies were modified from those proposed:

- Impacted payers must implement and maintain a Provider Access API beginning 2027, rather than 2026.
- Impacted payers are not required to share the quantity of items or services used under a prior authorization via the Provider Access API.
- Impacted payers are not required to share unstructured documentation related to prior authorizations via the Provider Access API.
- Impacted payers are required to provide educational resources to patients no later than one week after the start of coverage, rather than at enrollment.
- The educational resources that impacted payers are required to provide to patients and providers are described as "plain language" rather than in "non-technical, simple, and in easy-to-understand language."

C. Payer-to-Payer API

1. Background and Summary

CMS reviews the benefits of patients having complete records available at the point of care. Although a patient may have several providers, they usually maintain a relationship with only one or two payers during a year. Thus, payers are uniquely positioned to collect and aggregate patient data. When a patient moves to a different payer, sending patient data from the previous payer to the new payer is a powerful way to ensure data can follow the patient through the healthcare system.

This final rule requires, as of 2027, impacted payers to implement and maintain a payer-to-payer data exchange using a FHIR API that meets certain standards (described in section II.G.) with a patient opt-*in* policy. CMS notes that each payer would only be responsible for its own side of a transaction. For example, if an impacted payer is required to request patient data from another payer that is *not* an impacted payer, the impacted payer must make that request regardless of the other payer's status. In response to comments, the agency is also finalizing a modification to only require impacted payers to exchange data with a date of service within 5 years of the exchange request.

For this portion of the rule, certain terms apply:

- A patient's new payer is one in which the patient is newly enrolled and the payer is responsible for requesting and receiving the patient's data.
- Previous payers are where the patient previously had coverage and are responsible for sending data to the new payer.
- Concurrent payers are two or more payers providing coverage at the same time and thus are responsible for exchanging data with each other.

As with the other data exchanges in this rule, CMS is exploring steps for Medicare FFS to join in payer-to-payer data exchange. The agency says that it intends to implement the Payer-to-Payer API capability in Medicare FFS and strongly encourages all payers not subject to this rule to consider the value of implementing a Payer-to-Payer API, so that all patients, providers and payers in the U.S. health care system may experience the benefits of such data exchange.

Comments/Responses: Many commenters supported the proposal to require data exchange via a Payer-to-Payer API, stressing the benefits to patients of maintaining an ongoing record when they change payers. Others stated that the Payer-to-Payer API would be especially helpful to patients with concurrent coverage. CMS agrees that the benefits of payer-to-payer data exchange include both ensuring care continuity and that patients, providers, and future payers do not lose access to important health information. The agency finalizes, with modification, the Payer-to-Payer API proposals.

Other commenters opposed the Payer-to-Payer API proposals, disagreeing with CMS' justification that payers should be the maintainers of a patient's longitudinal data. Instead, patients should have the responsibility to maintain their patient data by leveraging the Patient Access API, using an app, or another solution of their choice. While CMS agrees that patients are in the best position to manage their health information, payers are uniquely positioned to collect and aggregate patient data, especially during coverage transitions. As previously noted, patients may have several providers who manage their care, but generally maintain a relationship with only one or two concurrent payers over the course of a full year (or more). Ensuring that payers have timely access to newly enrolled patients' data can have a multitude of benefits for patient care leading to better coordinated care, more informed decision-making, and minimized disruption in ongoing care. However, to mitigate potential burden on impacted payers, CMS will only require payers to exchange data with a date of service within 5 years of the request (rather than back to January 1, 2016, as proposed).

2. Proposal to Rescind 2020 Rule's Payer-to-Payer Data Exchange Policy

The May 2020 Interoperability and Patient Access final rule (85 FR 25568) required payer-to-payer data exchange, effective January 1, 2022, for impacted payers. Based on concerns raised by stakeholders about the lack of technical specifications, CMS announced in a December 10, 2021 Federal Register notification (86 FR 70412) that it would not enforce the payer-to-payer data exchange requirements until further rules are finalized. The agency now finalizes rescinding the payer-to-payer data exchange policy in that final rule, replacing it with the policies finalized here. CMS believes the use of FHIR APIs will ensure greater uniformity in implementation and more complete information.

Commenters supported CMS' proposal to rescind and replace the prior payer-to-payer requirements, agreeing that the proposals would help standardize data exchange and avoid developing duplicative systems. Multiple commenters strongly supported the new FHIR API approach, noting that it would leverage the same standards as the Patient Access and Provider Access APIs. CMS agrees that the degree of overlap between the requirements for the Patient

Access API and the Provider Access API should ease the development and implementation of the Payer-to-Payer API for payers.[22]

3. Payer-to-Payer Data Exchange on FHIR

a. Payer-to-Payer API Technical Standards

Because (as of January 1, 2021) the same adjudicated claims and encounter data and all data classes and data elements included in the standard at 45 CFR §170.213 were already required for the Patient Access API, the Patient Access API provides the foundation to share adjudicated claims and encounter data across the other APIs finalized in this rule. That is, payers have already devoted the development resources to stand up a FHIR API infrastructure when they implemented the Patient Access API, which can be adapted for additional interoperability use cases.

CMS finalizes that, beginning in 2027, impacted payers must implement and maintain a Payer-to-Payer API that is conformant with the same technical standards, documentation requirements, and denial or discontinuation policies as the Patient Access API. For the Payer-to-Payer API, impacted payers must use the following standards, described in greater detail in section II.G:

- 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).

One operational difference between the Patient Access and Payer-to-Payer APIs is that payers may find it more efficient to share data for multiple patients at a time for the Payer-to-Payer API. For example, impacted payers with a fixed enrollment period will have many patients' data to share at one time, especially if other payers share that enrollment period (such as QHPs offered on an FFE). In such a situation, it could require significant time and resources for payers to send each patient's data individually through an API. As mentioned above, the Bulk Data Access IG is a standard required for the Payer-to-Payer API for exchanging multiple patients' data at once and has been adopted by ONC at 45 CFR §170.215(d)(1), as discussed further in section II.G.

Comments/Responses: To prevent issues with data sharing across payers and allow information to be shared accurately and timely, multiple commenters expressed their support for reliance on the required standards (including some IGs) and recommended (but not required) IGs for the Payer-to-Payer API. In response to payers' implementation concerns, CMS states that it is extending the compliance date by a year (2027) from the original proposal (2026).

Other commenters raised a number of technical questions and concerns regarding various protocols and IGs, not described here. CMS refer readers to Table H3 in this final rule for an updated, finalized list of all required standards and recommended IGs for the Payer-to-Payer API. The agency says it will continue to work with ONC to advance the versions of the standards that ONC adopts at 45 CFR §170.215.

[22] Note that Payer-to-Payer API data content requirement also includes both structured and unstructured administrative and clinical documentation submitted by providers related to prior authorizations, of which the unstructured documentation is not required to be shared through the Patient Access and Provider Access APIs.

b. Payer-to-Payer API Data Content Requirements

As finalized, impacted payers must implement and maintain a Payer-to-Payer API to exchange claims and encounter data (excluding provider remittances and patient cost-sharing information), all data classes and data elements included in a content standard at 45 CFR §170.213 (USCDI), and certain information about prior authorizations—that is, consistent with the Patient Access API and the Provider Access API. In terms of some specific content, particularly around prior authorizations, the Payer-to-Payer API has some additional requirements, as described briefly below and in more detail in section II.D.

Comments/Responses: In response to comments, this final version is modified from the proposal by not requiring data related to denied prior authorizations and only requiring impacted payers to exchange data with a date of service within 5 years of the request (rather than the proposed start date of January 1, 2016). CMS says 5 years balances the needs to manage care continuity and establish a patient record with their new payer while not being overly burdensome on payers to exchange and maintain so much data that may not be relevant. CMS disagrees with suggestions for an even shorter period.

Multiple commenters recommended narrowing the scope of data that would be exchanged via the Payer-to-Payer API—for example, to specific data that would facilitate a change in coverage. CMS disagrees, saying that although care continuity is one purpose of the Payer-to-Payer API, there are other use cases that benefit from the additional information, including for purposes of the new payer's Patient Access and Provider Access APIs.

CMS reiterates that the Patient Access, Provider Access, and Payer-to-Payer APIs will all be required to include all data classes and data elements within that content standard that are maintained by the payer, based on the content standard at 45 CFR §170.213. The agency says it is not adding any requirements in this final rule that would require payers to parse and convert unstructured files into structured data, either for their own records or to share via the APIs; however, unstructured administrative and clinical documentation submitted by a provider to support a prior authorization request (excluding those for drugs and those that were denied) are required to be sent through the Payer-to-Payer API.

Specifically, CMS had proposed adding the following information about prior authorizations to the set of data that impacted payers must make available via the Payer-to-Payer API upon request from another payer:

1. The status of the prior authorization;
2. The date the prior authorization was approved;
3. The date or circumstance under which the authorization ends;
4. The items and services approved;
5. The quantity used to date; and
6. Related administrative and clinical documentation.

Multiple commenters supported this policy in order to increase transparency, improve care coordination, and reduce burden on providers, patients, and payers. For example, a commenter said that prior authorization information would enable the new payer to provide continuous coverage for existing treatments, which is especially important for patients receiving cancer

treatment and specific medications after progressing through step therapies. Multiple commenters expressed support for sharing historical data to increase payer knowledge of previous patient prior authorization decisions.

Other commenters recommended excluding some types of prior authorization data from the Payer-to-Payer API, particularly previously denied authorizations. After considering the comments, CMS is removing the requirement to include denied prior authorization decisions in the Payer-to-Payer API. However, supporting clinical information associated with such decision may be available under the requirement to share all data classes and data elements included in the data content standard at 45 CFR §170.213 (USCDI) maintained by the payer. Because a previously denied prior authorization decision generally would not reflect ongoing treatment, the value of including such information would likely be outweighed by the drawbacks of doing so, which CMS describes. The agency emphasizes, however, that denied prior authorization decisions are required to be shared via the Patient Access and Provider Access APIs because the benefits to those parties of accessing that information can be significant, especially for resubmitting requests or appealing decisions.

Several commenters also recommended not including the quantity of services used to date under a prior authorization, due to the concern that lagged health plan claims data may not be a reliable source to track the number of authorized services used to date. As previously discussed, this modification was also made for the Patient Access API and the Provider Access API.

Unlike the modification for the Patient Access API and the Provider Access API, CMS is finalizing that the Payer-to-Payer API must make available unstructured administrative and clinical documentation in order to promote greater continuity of care when patients change payers. For example, current data can allow a payer to authorize coverage for ongoing treatment without requiring repeat testing or needing a provider to resubmit clinical information that the provider has already submitted to a previous payer.

Another noteworthy difference with the Payer-to-Payer API is that typically payers only have to exchange data at the time a patient changes payers (or quarterly for concurrent payers). Thus, payers will have a longer timeframe to ensure that unstructured documentation is included in the patient's record and can be transferred to another payer when needed. Under the Patient Access and Provider Access APIs, payers have 1 business day from the time they receive the prior authorization request (or when there is another status update) to make prior authorization information available.

c. Identifying Previous and Concurrent Payers and Opt-In

CMS finalizes requirements that, beginning 2027, all impacted payers must develop and maintain processes to identify a patient's previous and/or concurrent payer(s). Patients or their personal representatives must be able to opt in to payer-to-payer data exchange (both with

previous and concurrent payers) within 1 week after the start of coverage—that is, for new enrollees—rather than at the start of coverage, as proposed.[23] Impacted payers will be required to allow a patient to report multiple previous and concurrent payer(s) and to request the patient's data from all previous and concurrent payers.

CMS outlines reasons why it is requiring an opt-in approach for the Payer-to-Payer API but opt-out for the others in this rule. In short, the other data exchanges in this rule involve the patient's current payer and providers who are in the payer's network; however, because the payer-to-payer data exchange likely involves parties who do not have a direct relationship with each other, the patient should have a larger gatekeeping role. Thus, the patient or their personal representative would need to affirmatively permit a payer to share data; without that permission, the payer could not engage in the payer-to-payer data exchange for that patient.

Comment/Response: Multiple commenters expressed concern regarding the proposed processes for opting in and collecting previous/concurrent payer data. CMS suggests there was some confusion because the proposed rule's preamble described the timing differently from the regulation text. CMS clarifies that payers must begin the process of collecting the previous payer information and the patient's election to opt in prior to the start of coverage, but that it may take longer than the enrollment process. It is modifying the regulatory text to identify the start of coverage (rather than enrollment) as the milestone for these requirements, consistent with the preamble discussion in the proposed rule.

This opt-in policy does not apply to data exchanges between a state Medicaid or CHIP program and its contracted managed care plans or entities. In addition, states, through their Medicaid and CHIP programs, would be responsible for collecting a patient's choice to opt into the payer-to-payer data exchange, rather than their contracted managed care plans. These managed care plans are still responsible for collecting previous/concurrent payer information and requesting the data exchange. Nothing in this rule prevents a Medicaid or CHIP agency from collecting that information and passing it along to their MCOs.

In response to related public comments, the agency is finalizing a modification by extending the deadline—for both (1) requesting identifying information about a patient's previous/concurrent payer(s) and (2) seeking opt-in from the patient—to 1 week after the start of coverage, with certain differences among payers. CMS emphasizes that payers must *begin* the process of collecting the previous/concurrent payer information and opt-in no later than 1 week after the start of coverage but understands that it may not be completed within that timeframe. The agency says it will rely on payers to develop reasonable processes to follow up with patients and recommends payers follow up one time before determining that the patient is choosing not to opt

[23] "Start of coverage" means when coverage begins or, if coverage begins retroactively (for example, for certain Medicaid enrollees), a later milestone, depending on the payer type, which the rule describes in detail for each payer. Where coverage starts prospectively, the deadline will be based on the coverage start date (also known as the coverage effective date). In the case of retroactive coverage, to avoid a deadline in the past, the deadline for the payer to provide the required information about the Payer-to-Payer API, request identifying information about previous/concurrent payer(s), and an opt-in will be based on the date that the payer gets patient information and makes the patient's coverage effective.

in. The patient education requirements (described in greater detail below) will provide patients annual reminders of the payer-to-payer exchange functionality.

Under the policy as proposed, an impacted payer would be required to:

- Allow a patient to report multiple previous/concurrent payers if they had (or continue to have) concurrent coverage, and
- Request the patient's data from all previous/concurrent payers.

Multiple commenters expressed concern with the lack of a standardized process to identify a patient's previous/concurrent payer(s) and provided various recommendations. However, because the requirements for a Payer-to-Payer API cross many payer programs with variation between enrollment processes, the agency determined that being prescriptive on a specific process would cause more implementation burden than necessary. Nevertheless, in response to comments, it is finalizing the modification to require payers to request previous and concurrent payer information no later than 1 week after the start of coverage, to allow additional time for payers.

Many commenters expressed support for the opt-in policy for the Payer-to-Payer API, citing various rationales. Others voiced concerns, stating that an opt-out framework would lead to more patient participation and more data available for the new payer, any new network providers, and the patients themselves. CMS agrees that an opt-in approach often results in fewer data exchanges, but a primary goal of the policy is to facilitate improved care, not solely increased data exchange. The agency believes that patients, as the owners of their data, should have control over who has access to their data, especially when the two parties exchanging patient data do not have a direct relationship with each other. For example, with the Provider Access API, the payer and provider have a network contract. CMS says patients should see value in having their data exchanged between their previous/concurrent payer(s) and their new payer, and impacted payers will be required to provide plain language information of the benefits of payer-to-payer data exchange and directions for opting in.

CMS points out that even if a patient chooses not to opt into the data sharing, payers may exchange information without a patient's authorization for other purposes, such as benefit coordination in the case of concurrent payers, or for other permissible reasons under the HIPAA Privacy Rule. Nothing in this rule prohibits payers from using the Payer-to-Payer API as the mechanism for data exchange permissible under other authority, even if the patient has not opted into the Payer-to-Payer API in this final rule.

d. Requesting and Responding to Data Exchange from a Patient's Previous/Concurrent Payer

CMS finalizes its proposal that impacted payers must request a patient's data from their previous/concurrent payer(s) no later than 1 week after the start of coverage—that is, for a new enrollee. If after the start of coverage—that is, for a current enrollee of the payer— the individual opts into the data exchange or provides previous/concurrent payer information or requests a payer-to-payer data exchange for another reason, then the current payer would be required to request data from the previous/concurrent payer(s) no later than 1 week after (a) the payer received the previous/concurrent payer information and the patient has opted in, or (b) the patient makes the request.

CMS acknowledges that the obligation to request data is contingent on the patient supplying the necessary information about a previous/concurrent payer; an impacted payer cannot comply with these requirements if the patient has not provided timely or accurate information about their previous/concurrent payer. In that case, payers are required to make reasonable efforts to gather this information from patients. Once again, CMS recommends that payers follow up one time before determining that the patient has not opted in. The finalized regulatory language is intended to clearly establish that the 1 week timeframe for requesting patient data begins when the impacted payer has sufficient identifying information about previous/concurrent payers and the patient has opted in.

CMS finalizes its proposal to require that the requesting impacted payer include an attestation with the request for data affirming that the patient (1) is enrolled with the requesting payer and (2) has opted in to the data exchange in a manner that meets the applicable legal requirements. When the current payer's request comes in (and if the specified conditions are met), previous/concurrent payers will be required to respond within 1 business day, consistent with the proposal.

While the agency is not requiring it, CMS encourages payers to supplement the data exchange required under this rule to account for any claims or data that are received *after* the initial data are sent to the new payer. Likewise, the agency encourages the new payer to send an additional request for data within 90 days of receiving the initial data response, to which the previous impacted payer would be required to respond.

If a previous/concurrent payer is not an impacted payer, they are not subject to this regulation and therefore are not required to send or request data through the Payer-to-Payer API or to respond to the request. This includes, for example, an employer-based commercial plan. A new or concurrent impacted payer is not obligated to determine whether the previous/concurrent payer is an impacted payer or to limit its requests for a patient's data to only impacted payers. If a payer not subject to this regulation:

- Does not have the capability to exchange the required data with an impacted payer;
- Refuses to exchange the required data with an impacted payer; or
- Is willing to exchange the data but is unable or unwilling to do so through a FHIR API,

then the impacted payer will not be required to exchange data with that payer.

Payers that have not implemented the Payer-to-Payer API would not have accessible digital endpoints to make the required request. CMS encourages all payers to implement a Payer-to-Payer API to support data exchange with other payers, even if they are not subject to these final requirements to support care coordination and more efficient operations.

e. Ongoing Data Exchange Requirements for Concurrent Coverage

For individuals with concurrent coverage from multiple payers, CMS proposed requirements for impacted payers to do the following:

- Collect identifying information about any concurrent payer(s) from patients *before* the start of coverage with the impacted payer,

- Request the required patient data[24] from all of a patient's concurrent payers no later than 1 week after the start of a patient's coverage,
- Send data within 1 business day of receiving a request that meets all the requirements of this final rule,
- Exchange with every other concurrent payer, at least quarterly, and
- Incorporate these data into the recipient payer's records about the patient.

CMS stated that this would ensure the patient's concurrent impacted payers maintain a complete patient record and can provide all the information required under the Patient Access and Provider Access APIs.

In response to comments, CMS modifies one aspect of its proposal: Concurrent payers' quarterly transmission need only include data updated since the last exchange. Any data previously transferred to another concurrent payer does not need to be included in the quarterly data exchange.

f. Data Incorporation and Maintenance

Data received by an impacted payer through the Payer-to-Payer API must be incorporated into the patient's record with the new payer. Those data could then be part of the patient's record maintained by the new payer and should be included as appropriate in the data available through the Patient Access, Provider Access, and Payer-to-Payer APIs. A patient's data could then follow them between payers and be available to them and their providers.

In the proposed rule, CMS noted that its proposals would not impact any payer's data retention requirements and did not propose to require impacted payers to maintain data for unenrolled patients any longer or differently than they do today under current law, regulation, or policy. Multiple commenters supported this decision, while others recommended a minimum data retention timeframe. CMS says it still does not believe that additional data retention requirements are necessary at this time, and it does not wish to change or create conflict with existing rules. The agency mentions, for example, that other regulations already require MA organizations, Medicaid managed care plans, and CHIP managed care entities to retain records for at least 10 years.

g. Patient Education Resources

Consistent with the requirements for the Provider Access API, CMS finalizes requiring that impacted payers (excluding Medicaid and CHIP MCOs[25]) provide patients with educational resources in "plain language" (modified from the proposed "non-technical, simple, and easy-to-understand language"). These resources must explain, at a minimum, the benefits of the Payer-

[24] As described in section II.C.3.b. above, the finalized content requirements are claims and encounter data (excluding provider remittances and cost-sharing information), all data classes and data elements included in a content standard at 45 CFR §170.213 (USCDI), and certain information about prior authorizations that the payer maintains with a date of service within 5 years of the request.

[25] State Medicaid and CHIP programs will provide this information to beneficiaries and will be responsible for collecting beneficiaries' permission for payer-to-payer exchange.

to-Payer API data exchange, patients' ability to opt in or withdraw their permission, and instructions for doing so.

These educational resources must be provided at or before requesting permission for the Payer-to-Payer API data exchange. Currently enrollees must be given the opportunity to opt in to the payer-to-payer data exchange and to provide previous/concurrent payer information before the API compliance dates. Impacted payers will be required to provide these educational resources to current enrollees at or before requesting their opt-in, as well. Similar resources must also be provided annually to all covered patients in mechanisms that the payer regularly uses to communicate with patients and to post these resources in an easily accessible location on the payer's public website.

The compliance date for providing these resources is also being moved to 2027.

4. Payer-to-Payer Data Exchange in Medicaid and CHIP

The 2020 CMS Interoperability and Patient Access final rule (85 FR 25568) did not require state Medicaid and CHIP FFS programs to implement the payer-to-payer data exchange, but this rule applies the requirement to those programs. CMS says that requiring state Medicaid and CHIP FFS programs to implement the Payer-to-Payer API data exchange in this rule would not be as burdensome as the non-API-based payer-to-payer data exchange that was finalized in the CMS Interoperability and Patient Access final rule, which CMS is now rescinding. State programs should have already implemented Patient Access APIs and should thus be able to leverage the work done for that API to make implementing this new API more manageable.

CMS finalizes that, like other impacted payers, state Medicaid and CHIP agencies establish a process to allow beneficiaries to opt in to the payer-to-payer data exchange. These agencies (not their MCOs) are also responsible for obtaining required permissions and identifying patients' previous/concurrent payers.

Comments/Responses: Multiple commenters recommended that CMS reexamine whether its interpretation of 42 CFR §431.306(d) and 42 CFR §457.1110(b) would prohibit Medicaid agencies from participating in HIEs, particularly for the purposes of the Payer-to-Payer API. CMS says it does not agree that 42 CFR §431.306(d) and 42 CFR §457.1110(b) prohibit Medicaid or CHIP agencies from contracting with an entity that offers the technology to allow for digital access and transfer of a patient's medical records, often referred to as an HIE. CMS then proceeds to provide a lengthy analysis and explanation of its position. The agency says Medicaid and CHIP agencies are welcome to contract with HIEs or HINs, especially those operating under TEFCA, to facilitate payer-to-payer data exchange. Further, while nothing in this rule would prohibit a Medicaid/CHIP agency from partnering with an HIE to meet its requirements, Medicaid/CHIP agencies must continue to comply with all other federal requirements applicable to the operation of Medicaid and CHIP.

One commenter stated that an opt-in process implemented within its system would not authorize another payer (particularly payers not subject to this regulation) to release patient information to the commenter or for the commenter to release a patient's data to a patient's subsequent payer.

CMS says it is finalizing that when another payer (including a payer not subject to this final rule) requests a former Medicaid/CHIP beneficiary's information from the state agency, an attestation from a requesting payer that the patient or their representative has opted in to data exchange with the requesting payer (that is, given permission for the Medicaid or CHIP agency to share the beneficiary's data) is sufficient to meet the requirements at 42 CFR §431.306 and 42 CFR §457.111(b) to allow the state Medicaid/CHIP agency to respond to the data request. Such permission must be received prior to the state Medicaid or CHIP agency sharing any beneficiary data.

Multiple commenters agreed with the proposal for state Medicaid/CHIP agencies to collect and manage patient decisions to opt in to the payer-to-payer data exchange when beneficiaries are enrolled in Medicaid/CHIP managed care. Many also agreed that collecting a beneficiary's choice to opt in to the payer-to-payer data exchange as part of existing Medicaid/CHIP eligibility and enrollment processes would be the most effective and technically feasible approach for most states operating managed care programs and would streamline the process for beneficiaries. CMS agrees and additionally observes that because higher rates of opt-in are expected when patients are presented with the option at a point when they are already providing information (such as at application or plan selection), CMS highly encourages states to leverage any touchpoints before patients are enrolled rather than expecting patients to opt in through a separate process.

A commenter requested clarification on whether a patient's opt-in permission is required to share data between impacted payers *within* the same state Medicaid program. In response, CMS says that Medicaid and CHIP managed care plans are not "outside sources" as described at 42 CFR §431.306(d) but are part of a state's Medicaid/CHIP programs as a whole, because these entities are contracted to support the agency's administration of its Medicaid or CHIP state plan. Thus, CMS is finalizing the proposal that if a Medicaid or CHIP agency is exchanging information per the Payer-to-Payer API requirements with a managed care plan with which they have a contract (including D-SNPs), the requirement to obtain patient opt-in would not apply.

5. Final Action and Statutory Authorities for Payer-to-Payer API

CMS again summarizes the finalized requirements for the Payer-to-Payer API,[26] along with the rationale for the policies and the underlying statutory authority for each of the impacted payer types. The following policies were modified from those proposed:

- Impacted payers must implement and maintain a Payer-to-Payer API beginning in 2027, rather than in 2026.
- Impacted payers are not required to share the quantity of items or services used under a prior authorization via the Payer-to-Payer API.
- The data exchange between a previous payer and a new payer is limited to data with a date of service within the previous 5 years.

[26] As part of this, CMS is finalizing the rescission of the payer-to-payer data exchange policy previously finalized in the CMS Interoperability and Patient Access rule (85 FR 25568) at 42 CFR §§422.119(f)(1) and 438.62(b)(1)(vi) and (vii) and 45 CFR §156.221(f)(1).

- Impacted payers are required to request patients' permission for payer-to-payer data exchange and identifying information about patients' previous/concurrent payers no later than 1 week after the start of coverage, rather than at enrollment.

D. Prior Authorization API and Improving Prior Authorization Processes

1. Background

This section of the rule finalizes polices for prior authorization that are intended to improve the prior authorization processes for payers, providers, and patients. The following policies are finalized for impacted payers and are detailed further below; impacted payers must do all of the following:

- Implement and maintain an API to support and streamline the prior authorization process;
- Respond to prior authorization requests within certain timeframes;
- Provide a specific reason for prior authorization denials; and
- Publicly report on prior authorization approvals, denials, and appeals.

CMS uses the term prior authorization (PA) to refer to the process by which a provider must obtain approval from a payer before providing care in order to receive payment for delivering that care. While the agency believes PA has an important role to play in the health care system, obtaining PA can be challenging for patients, providers, and payers. Dissimilar payer policies, inconsistent use of electronic standards, and other technical barriers have created provider workflow challenges and an environment in which the PA process is a primary source of burden, which may create health risks for patients and contribute to provider burnout. The policies finalized in this rule apply to any formal decision-making process through which impacted payers render an approval or denial determination in response to a PA request based on the payer's coverage guidelines and policies before services are rendered or items provided.

CMS clarifies that its finalized PA policies do not apply to any drugs that could be covered by the impacted payers, including prescription drugs that may be self-administered, administered by a provider, or dispensed or administered in a pharmacy or hospital. The PA policies do not apply to over-the-counter (OTC) drugs that may be covered by a payer nor do they apply to covered Part D drugs under the Medicare Part D benefit.

Additionally, CMS reminds readers that the PA policies finalized in this rule do not directly affect the Medicare fee-for-service (FFS) program though it will evaluate whether the automation of prior authorization processes under Medicare FFS may be improved.

Effective Dates. CMS finalizes its proposed 2026 compliance deadline for the new requirements (1) to reduce decision timeframes for standard and expedited PA decisions, (2) to provide a specific reason for a PA denial, and (3) to require public reporting of certain PA metrics.

A 2027 compliance date is finalized for the Prior Authorization API. CMS cites the time likely needed by a variety of payer types and sizes to implement and test the Prior Authorization API as its rationale to finalize the 2027 compliance date for this API. Implementation activities would

include payer collaboration with EHR vendors to support connections for their providers and the development of outreach materials.

Comments/Responses: CMS reports that of the nearly 900 comments received on the proposed rule, the majority addressed the PA proposals. Many comments urged finalizing the proposals as soon as possible; some commenters were concerned by proposed compliance timelines, PA decision timeframes, and reporting metrics. CMS was urged by some stakeholders to develop a broader set of requirements, including with respect to the content of PA requests. The agency responds that it addressed some of these concerns in its CY 2024 MA and Part D final rule (88 FR 22120), which will streamline prior authorization requirements, add continuity of care requirements, and, CMS believes, reduce disruptions for Medicare beneficiaries enrolled in MA plans. Many commenters pushed for automating the PA process and encouraged CMS to examine bundled prior authorizations for an episode of care requiring multiple PAs. While the agency encourages innovation, it wants innovation to be secure and to include a role for medical professional judgment as well as oversight and transparency. Some commenters worried that payers may charge a fee to use or access the payer's Prior Authorization API; CMS notes that it did not address this issue and encourages payers not to charge providers more for costs associated with the APIs, including transaction costs.

Other comments stressed the need for APIs to be integrated with EHR systems, and the lack of standardized coding and structured data in provider EHRs makes adjudicating a PA request problematic. In response, CMS says this is an industry readiness issue, and it believes over the next few years, both provider management systems, as well as certified EHRs, will advance in their use of standards, data exchange, and connectivity.

2. Requirement to Implement an API for Prior Authorization

a. Prior Authorization API

CMS had proposed to require certain payers to implement and maintain a FHIR Prior Authorization Requirements, Documentation, and Decision API, or PARDD API to facilitate the prior authorization process for all prior authorization rules and requirements for items and services, other than drugs. The proposal is finalized with modifications to the name and a one-year delay in the implementation date.

A Prior Authorization API must:

- Be populated with the payer's list of covered items and services, excluding prescription drugs and/or covered outpatient drugs, that require prior authorization.
- Identify all documentation required for approval of any items or services that require prior authorization.
- Support a HIPAA-compliant prior authorization request and response.
- Communicate whether the payer approves the prior authorization request (and the date or circumstance under which the authorization ends), denies the prior authorization request (with a specific reason), or requests more information.

Generally, impacted payers must comply with the API requirement beginning January 1, 2027. The compliance date for Medicaid managed care plans and CHIP managed care entities is the

rating period beginning on or after January 1, 2027, and for QHP issuers on the FFEs, for plan years beginning on or after January 1, 2027.

CMS believes that the Prior Authorization API will make prior authorization requirements and documentation requirements more accessible and transparent to providers at the point of care. Providers may use the API to query the PA requirements for specific items and services to identify documentation requirements, to complete electronic forms and templates, or to link elsewhere to submit the documentation. This API will improve electronic data exchange between impacted payers and providers once provider practice management systems or EHRs connect with the API. CMS believes providers are eager to access this type of technology to replace the numerous web portals and fax numbers used to submit PA requests currently. The policies finalized in this section are specific to the PA process between payers and providers; CMS believes the API will streamline the process by automating some tasks.

Comments/Responses: Commenters were supportive of the proposed API for the efficiencies, transparency and ultimate transition to electronic prior authorization they believe it will engender. CMS notes it did not propose a requirement for real-time PA determinations, but it believes the level of automation could improve processing timeframes in the future. The agency acknowledges that implementation challenges, such as identifying all policies and authorization processes that would be included in the Prior Authorization API as well as the costs of digitizing those policies and processes, will likely initially increase burden on payers. Also, possible workflow changes for providers and payers to translate medical information from non-FHIR systems for use in the Prior Authorization API will increase burden and costs. CMS explains that these comments motivated the one-year delay in the compliance dates, and it believes over time the Prior Authorization API will achieve efficiencies for all parties and improve transparency and access to care.

b. FHIR Implementation Guides

CMS finalizes its proposal to require certain API standards[27] that are adopted at 45 CFR 170.215 and to recommend the use of certain IGs to implement the Prior Authorization API.[28] See Table H3 in the preamble for a full list of the required standards and recommended IGs to support API implementation. Impacted payers may use updated standards, specifications, or IGs that are not yet adopted in regulation for the APIs in this final rule—subject to certain conditions (see section II.G. below). Commenters took different positions on whether to require versus recommend the IGs, on the maturity of the IGs, and on the technical implementation challenges of the IGs. Full testing of the IGs before the effective date of the final rule was encouraged. Some commenters observed that more than one technology solution may be required for payers and providers to participate and track activity using the Prior Authorization API. CMS says it is affording

[27] These standards are IGs adopted as implementation standards and include HL7 FHIR Release 4.0.1, US Core IG STU 3.1.1, and SMART App Launch IG Release 1.0.0.
[28] These IGs include the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide, the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR) Implementation Guide, and the HL7 FHIR Da Vinci Prior Authorization Support (PAS) Implementation Guide.

flexibility by not requiring these IGs, and it notes that they have been updated since publication of the proposed rule.

c. Existing Prior Authorization Standards: HIPAA Exceptions for Testing New Standards

Existing HIPAA transaction standards for the electronic exchange of information by covered entities include prior authorization transaction standards (i.e., standards for referral certifications and authorizations). These are the X12 278 transaction standard (Version 5010) and NCPDP D.0 for electronic prior authorization transactions. However, they have not achieved a high adoption rate by covered entities.[29] Payers instead build proprietary interfaces and web portals through which providers submit their requests, and both still frequently resort to phone calls or faxes to complete the process for a response. CMS believes enhancements to the electronic PA process could support greater use of the HIPAA X12 278 standard through automation, which could also reduce the time for submission of the request and response.

CMS notes new operating rules for the PA standard have not been adopted, and in June 2023, the National Committee on Vital and Health Statistics (NCVHS) recommended that HHS not adopt the proposed CAQH CORE Attachments Prior Authorization Infrastructure operating rule or the CAQH CORE Attachments Health Care Claims Infrastructure operating rule. The NCVHS believes adoption of those rules should be considered only after publication of a final rule adopting a health care attachments transaction standard under HIPAA.

In March 2021, HHS approved an application from an industry group of payers, providers, and vendors for an exception under 45 CFR 162.940 from the HIPAA transaction standards. The exception permits testing of proposed modifications to the PA standard. Under this exception, the group is testing a prior authorization exchange using the HL7 FHIR standard without the X12 278 standard over a 3-year period to determine whether this alternative standard for prior authorization could improve efficiency. CMS notes that unless an impacted payer is included in the current pilot to test an exception to the HIPAA transaction, that payer may be required to use the adopted HIPAA standard when implementing the API.

d. Federal Matching Funds for Expenditures of State Medicaid and CHIP FFS Programs and Medicaid Expansion CHIP Programs on Implementation of the Prior Authorization API

Policies relating to federal matching funds to support implementation of the Prior Authorization API by state Medicaid and CHIP FFS programs and by Medicaid Expansion CHIP programs are discussed in section II.E. of the final rule and described in section II.E. of this summary below.

[29] CMS cites data from the Council for Affordable Quality Healthcare annual report for 2019 indicating that 13 percent of respondents indicated they were using the standard in a fully electronic way; 54 percent were conducting electronic prior authorization using web portals, Integrated Voice Response and other options, and 33 percent were fully manual (phone, mail, fax, and email). https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf?token=SP6YxT4u. The 2021 annual report shows an increase of use of the X12 278 prior authorization standard from 13 to 26 percent.

3. Requirement for Payers to Provide Reason for Denial of Prior Authorizations and Notifications

a. Reason for Denial of Prior Authorization

Beginning January 1, 2026 (for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2026, and for QHP issuers on the FFEs, for plan years beginning on or after January 1, 2026), impacted payers must provide a specific reason for denied PA decisions (other than for drugs), regardless of the method used to send the PA request. Also, as noted above, responses about a PA decision sent through the Prior Authorization API from the payer to the provider must include information regarding whether the payer approves (and for how long) or denies the PA request, or requests more information from the provider to support the request.

b. Denial Reason and Denial/Decision Codes

Some payers, such as MAOs, that are subject to this new requirement must still comply with other laws and regulations that require notice to patients, providers or both of the specific reason for a PA denial. Further, existing communication requirements related to coverage decisions, notices of coverage decisions, and appeal processes remain in effect for coverage decisions that are made as part of a PA denial or approval. They are not superseded by the policies established in this final rule. In response to a request, CMS defines the terms "approval," "denial," and "specific reason" vis-à-vis PA denials in the preamble but not the regulation text. They are defined as follows:

- *Approval*: When a payer authorizes coverage of items or services for which PA has been requested.
- *Denial*: The refusal by a payer to approve the PA for a health care item or service. Denials (or rejection of a PA) may result because the service was not considered medically necessary under the payer's medical guidelines or the provider did not provide complete or accurate documentation to support the request.
- *Specific Reason*: Specific reasons for a denial include the following:
    - Reference to the specific plan provisions on which the denial is based;
    - Information about or a citation to coverage criteria;
    - How documentation did not support a plan of care for the therapy or service; and
    - A narrative explanation of why the request was denied, and specifically, why the service is not deemed necessary or that claim history demonstrated that the patient had already received a similar service or item.

Comments/Responses: Multiple commenters suggested that CMS further specify the level of detail payers must provide about the reason(s) for the denial, such as the policy on which the decision was based, the standards used to determine medical necessity, the clinical rational and patient-specific information supporting the decision, whether the decision was automatically adjudicated, whether algorithms were used, and whether a human decision-maker was involved. CMS does not change the level of detail required though it does affirm that all denial reasons must be specific. The agency notes that other federal law and regulation may require more

information, citing the changes and clarifications made by the CY 2024 MA and Part D final rule (88 FR 22120) for MA plan coverage criteria and PA requirements. CMS notes that the X12 Service Decision Reason Code List is a code set maintained by X12 for electronic PA decisions and that updates to the code set are requested through the X12 code maintenance workgroup.

c. Existing Notice Requirements to Communicate Prior Authorization Denial Information — By Program

Some payers are currently required under federal or state law to provide notice to patients or providers, or both, with the specific reasons for denial. CMS says the requirement it finalizes in this rule builds on those existing policies, and it does not modify or replace existing requirements to provide notice to patients or providers, or both.

MA program regulations specify the form and content of the written notice to enrollees in the event of an organization determination that results in a partial or full denial of items or services and the deadlines by which notice must be sent to both the enrollee and their physician. Under the final rule, beginning January 1, 2026, MAOs must also comply with this new requirement when an enrollee requests PA using the Prior Authorization API. Similarly, CMS applies the same policies regarding PA processes that it finalizes for MA plans and Medicaid managed care plans to applicable integrated plans.[30] The new requirement does not change the content requirements for written denial notices to enrollees from these integrated plans; rather, it supplements them by requiring the plans to notify the provider of the reason for a denial of a PA request.

For Medicaid managed care plans and CHIP managed care entities, CMS finalizes its proposal that a response to a provider with respect to a PA request, if transmitted via the Prior Authorization API workflow process or other means, will satisfy current notice to provider requirements under 42 CFR 438.210(c). The responses could be whether the authorization request has been approved (and for how long), denied (with the reason for the denial), or a request for more information to support the prior authorization. Payers will not have to send the response to a provider via both the Prior Authorization API process and a separate, additional notice in another manner with duplicate information. However, payers must ensure that the response is in fact given to the provider through some means. Further, CMS reminds these payers they must still provide a separate written notice to the enrollee.

CMS notes that QHP issuers on the FFEs that offer individual health insurance must provide the specific reason for an adverse benefit determination, which includes a PA denial.

The agency reiterates several times that the PA requirements finalized in this rule supplement and do not replace requirements in other applicable laws, including existing requirements for MA plans, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs regarding decisions made on requests for prior authorization of covered benefits.

[30] An applicable integrated plan, as defined at 42 CFR 422.561, is either a fully integrated or highly integrated Dual Eligible Special Needs Plan (D-SNP) with exclusively aligned enrollment with a Medicaid managed care organization.

4. Requirements for Prior Authorization Decision Timeframes and Communications

a. Impact of Delays in Prior Authorization Decisions: Background and Overview of Current Decision Timeframes

Providers have expressed concerns about the impact of delays in PA decision making by plans on patient care, including creating unnecessary medical risk. The agency received a great deal of feedback complaining about the timeframes for processing PA decisions.

CMS uses the term "standard" prior authorization to refer to non-expedited, non-urgent requests for prior authorization and the term "expedited" prior authorization to indicate an urgent request. Some commenters asked for more specificity in defining these terms, but CMS believes the meaning of the terms has already been sufficiently established in federal regulations.

Table 4 in the preamble to the proposed rule showed the current deadlines for these decisions under federal regulations, where applicable; not all the regulations provide for a deadline. Generally, the regulations require a PA decision for an expedited request to be completed as expeditiously as a patient's health condition requires and no later than 72 hours, and for a standard request within 14 days. Some regulations permit extensions with associated additional timeframes and requirements for beneficiaries and payers, respectively.

b. Decision Timeframes for Standard and Expedited Prior Authorization Requests

Effective January 1, 2026, CMS finalizes its proposal to change the deadlines for PA decisions as follows:

- Standard requests: Notice of decisions by MA organizations and applicable integrated plans, Medicaid FFS programs, and CHIP FFS programs must be provided as expeditiously as a patient's health condition requires, but no later than 7 calendar days.
- Expedited requests: Notice of decisions by Medicaid FFS programs, and CHIP FFS programs must be provided as expeditiously as a patient's health condition requires, but no later than 72 hours unless a shorter minimum time frame is established under state law.

Federal regulations currently impose a 72-hour deadline for expedited decisions made by MAOs, applicable integrated plans, Medicaid managed care plans, and CHIP managed care entities. The finalized policies do not change the existing regulations for these plans nor do they impact the current authority for an extension of the deadline under those regulations. CMS did not propose to change existing federal timeframes for standard and expedited determinations on requests for Part B drugs for MA plans and applicable integrated plans. Additionally, MA plans must automatically transfer a request to the standard timeframe if the MA plan denies a request for an expedited organization determination or an applicable integrated plan denies a request for an expedited integrated organization determination.

For MA plans and applicable integrated plans, the current timeframes continue to apply to enrollee notices, and for Medicaid managed care plans and CHIP managed care entities, existing regulation requires that notices must be provided to both the provider and to the enrollee. CMS did not propose to change timeframes for PA processes for QHPs on the FFEs.

State laws that impose a shorter timeframe for these decisions will govern for Medicaid FFS, CHIP FFS, Medicaid managed care plans, and CHIP managed care entities. Under the final rule, if a state law imposes a longer time frame, CMS indicates that payers must comply with the shorter federal deadline. State laws do not apply to MA plans because of federal preemption rules in the statute and regulations; thus, MA plans are only required to comply with timeframes set under federal regulation.

CMS clarifies that impacted payers are not required to approve a request for PA if that payer did not meet the required standard or expedited decision timeframe. In these cases, providers should contact the payer for information on the status of the request to determine the reason for the failure to meet the deadline. Under the MA program, and the Medicaid and CHIP managed care programs, such a failure constitutes an adverse decision that may be appealed.

Comments/Responses: Objections were raised to the proposal to exclude QHP issuers on the FFEs from the shortened timeframe requirements. CMS responds that issuers of all non-grandfathered group and individual market plans or coverage must meet minimum internal claims and appeals standards, and the agency believes the current standard adequately protects patients. Some commenters advocated for a shorter timeframe than 7 calendar days for standard PA requests, especially for timely approvals for discharge to an appropriate post-acute care setting. CMS believes 7 days, which it notes is the maximum timeframe, affords payers the time to consider patient-specific information. Some commenters warned that the shorter timeframes could result in more denials due in part to the need for more administrative staff and resources. CMS believes this could be the case initially but that over time improvement to the PA process will result in efficiencies. The agency reiterates that Medicaid managed care plans and CHIP managed care entities may have an extension of up to 14 additional calendar days (to the 7-calendar day timeframe) if the enrollee or the provider requests the extension or if the managed care plan justifies a need for additional information and how the extension is in the enrollee's interest.

Table E1 in the preamble of the final rule shows the final federal requirements for PA decision timeframes that will apply to each payer beginning in 2026.

5. Requirements for Timing of Notifications Related to Prior Authorization Decisions

a. MA Organizations

Effective January 1, 2026, CMS finalizes its proposal to require MAOs, beginning January 1, 2026, to notify enrollees of a standard pre-service organization determination (including prior authorizations) for a medical item or service as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after the organization receives the request for the determination. This also applies to determinations by applicable integrated plans. Additionally, applicable integrated plans that deny a request for an expedited determination and automatically transfer the request to the standard timeframe would have to make the determination within the 7-calendar day timeframe, rather than the current 14-calendar day timeframe for an integrated organization determination. These changes also apply to applicable integrated plans that are Medicaid MCOs.

CMS did not propose to change the current 72-hour decision timeframe for expedited requests or the availability of the 14-calendar day extension to make a determination for standard requests and for expedited requests.

b. Medicaid Fee-for-Service, Including Beneficiary Notice and Fair Hearings

CMS clarifies that under its longstanding policy, existing Medicaid notice and fair hearing rights apply to all Medicaid FFS prior authorization decisions. That is, under current regulations a partial or total denial of a PA request is appealable through a state fair hearing.

In addition, under the final rule effective January 1, 2026, notice of the state Medicaid program's decision regarding an expedited request for PA must be communicated as expeditiously as a beneficiary's health condition requires, but no later than 72 hours after receipt of a provider's request for an expedited determination, unless state law establishes a shorter minimum time frame. Notice of a decision on a standard request for PA must be communicated to the requesting provider as expeditiously as a beneficiary's health condition requires, but no later than 7 calendar days after receiving the request, unless state law establishes a shorter minimum time frame. The decision-making and communication timeframe for a standard request may be extended by up to 14 calendar days if the state requires additional information or upon request by the provider or beneficiary.

Under current regulations, a state must provide an individual at least 10 days' notice prior to taking any action that includes termination, suspension, or reduction in benefits or services for which there is a current approved prior authorization, and the state must afford the beneficiary the right to continuation of services pending resolution of the state fair hearing. CMS finalizes what it describes as clarifying updates to the regulations to make it explicit that the existing Medicaid beneficiary notice and fair hearing rights apply to Medicaid FFS PA decisions, independent of the notification timeframe finalized in the rule. These changes apply as of the effective date of the final rule, but any notice or fair hearing right that is based solely on the new policies finalized in this rule take effect January 1, 2026.

CMS clarifies that the Medicaid beneficiary notice requirements at 42 CFR 435.917 and 431.210 through 431.214, including all revisions and additions finalized in this rule, apply to the written notice provided by the state to the beneficiary. It also notes that current application of existing notice and fair hearing requirements to Medicaid FFS PA decisions, including the clarifications, is consistent with current regulations for notice and appeal rights for managed care PA decisions. The sections of the regulations modified in the final rule are listed in Table E2 in the preamble.

c. Medicaid Managed Care

Effective for rating periods that start on or after January 1, 2026, CMS finalizes its proposal to require Medicaid managed care plans to provide notice of standard PA decisions as expeditiously as the enrollee's health condition requires and within state-established timeframes that may not exceed 7 calendar days following the plan's receipt of the request for service. Current rules remain in effect for rating periods beginning before January 1, 2026. CMS did not propose any changes to the timeframes for expedited decisions; however, in the final rule, it clarifies that

MCOs, prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) must make these decisions on shorter timeframes if the state requires them. No changes were proposed to the current authority for the 14-calendar day extension to make a determination for standard requests and for expedited requests.

CMS reiterates that its finalized policies do not change the current regulatory provisions that treat the failure to issue a decision within the required timeframe as an adverse benefit determination, which is appealable.

d. CHIP Fee-for-Service and Managed Care

Beginning January 1, 2026, decisions related to PA of health services under the CHIP FFS and Managed Care programs must be completed in accordance with the medical needs of the patient, but no later than 7 calendar days after receiving a request for a standard determination and not later than 72 hours after receiving a request for an expedited determination. If a beneficiary requests an extension of a PA review, or if the provider or health plan determines that additional information is needed for such review, an extension of up to 14 calendar days would be permitted.

In response to comments, CMS indicates that it will work with state Medicaid and CHIP FFS programs that may be unable to meet the new PA decision timeframes compliance date in 2026. States should contact their Medicaid state lead or CHIP project officer before April 1, 2025, to discuss the extenuating circumstances. Any flexibility granted to a state Medicaid or CHIP FFS program for the implementation of the new PA decision timeframe requirements will be temporary and limited to the unique circumstances of the program.

CMS finalizes its proposal to establish a federal maximum timeframe for PA requests. States with shorter deadlines may enforce those shorter timeframes for these requests. Tables E2 and E3 in the final rule provide a list of some, but not all, of the final policies for decision notification timelines for the impacted payers. The full list of final policies and citations is included in Table E4.

e. QHPs on FFEs

CMS did not propose to extend these timeframes to QHPs on FFEs because it believes that doing so could result in burdensome and conflicting regulatory standards given the existing standards at 45 CFR 147.136(b)(3) regarding internal claims and appeals standards.

6. Public Reporting of Prior Authorization Metrics

Under the final rule, impacted payers must publicly report certain aggregated prior authorization metrics on their websites. CMS does not collect these data; the requirement is for an impacted payer to post the data on the payer's website.

For Medicare Advantage, reporting will be at the contract level; this is a change from the proposed rule that would have required reporting at the organizational level. Integrated care

plans will report items and services covered by MAOs at the MA contract level and will report items and services covered by Medicaid managed care plans at the plan level; this is due to the separate requirements for MAOs and Medicaid managed care plans under the respective contracts. Where there is not a clear delineation between whether items or services are covered under Medicare or Medicaid (e.g., home health services), CMS will accept any reasonable methodology for attributing the PA reporting from an integrated plan to one payer versus the other. For Medicaid and CHIP FFS programs, the reported data is at the state level. Reporting will be at the plan level for Medicaid and CHIP managed care and at the issuer level for QHP issuers on the FFEs.

Prior authorization data will be compiled from multiple sources, on multiple measures and individuals, and compiled into aggregate data, or summary data, for purposes of public reporting and statistical analysis. Specifically, impacted payers must publicly report all of the following metrics at least annually.

- A list of all items and services that require PA.
- The percentage of standard PA requests that were approved, aggregated for all items and services.
- The percentage of standard PA requests that were denied, aggregated for all items and services.
- The percentage of standard PA requests that were approved after appeal, aggregated for all items and services.
- The percentage of PA requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited PA requests that were approved, aggregated for all items and services.
- The percentage of expedited PA 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 PAs, 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 expedited PAs, aggregated for all items and services.

CMS did not propose to require payers to report on categories of items and services, but rather aggregate the information as totals or percentages of total items and services. No specific format for how payers should present the aggregated data was proposed, but CMS encourages impacted payers to consider readability and accessibility.

Each year, the data must be reported publicly by the end of the first calendar quarter for the prior year's data. For example, for all impacted payers, all available data for calendar year 2025 must be publicly reported by the end of the first calendar quarter of 2026 (i.e., March 31, 2026).

CMS believes that public reporting of this information will help inform patients and providers about payers. Patients may consider access to care in choosing a plan, and providers may consider information on PA decisions useful when deciding whether to contract with a plan or join a network.

Comments/Responses: Requests for more granular data in the reports were received, such as a suggestion that MAOs report metrics at the plan level. CMS finalized a change to require MAOs to report at the contract level, which generally have multiple MA plans. MAOs already annually report some contract-level data, and MA Star Ratings are also assigned at the contract level. CMS is also concerned about data overload, patient understanding, and usability of data, but it indicates it may consider requiring more granular data in future rulemaking. Some commenters sought a delay in, or phase in of, the reporting requirements given the fact that the Prior Authorization API will not be required before January 1, 2027; CMS declines to delay this reporting.

Concerns were expressed that PA policies and information on the publicly reported metrics could be used inappropriately for improper decision-making purposes or other reasons, such as plans "self-selecting" patients by implementing other burdensome PA processes to avoid approving services, which could lead to patients who need those services enrolling in other plans. CMS believes this is an unlikely outcome, and it points to protections against this type of plan behavior under current regulations, including antidiscrimination laws and regulations. Some commenters suggested that CMS should report this information on its website; the agency believes patients are more likely to view their plans and payers as the resource for this data. However, CMS encourages state Medicaid agencies to include the data on their websites. Some commenters recommended requiring service-specific reporting or setting-specific reporting, which they believe will help identify services for which there is a high rate of approval and for which PA requirements may no longer be necessary, or for identifying critical services or items being routinely denied. CMS declines to adopt this recommendation at this time due to concerns about patients being overwhelmed by too much data.

Table E4 in the preamble of the final rule shows the sections of the regulations that will be changed by the finalized policies for each impacted payer type.

E. Extensions, Exemptions, and Exceptions and Federal Matching Funds for Medicaid and CHIP

1. Extensions and Exemptions for Medicaid and CHIP FFS Programs

For state Medicaid and CHIP FFS programs, CMS finalizes its proposals for a one-time extension or an exemption for the Provider Access, Payer-to-Payer and/or Prior Authorization APIs required under this rule.

a. Extensions

A request for an extension of the compliance deadline is for a period of up to year. States must submit a written application for the one-time extension, which must include the following information:

- A narrative justification describing the specific reasons why the state cannot satisfy the requirement(s) by the compliance dates, and why those reasons result from circumstances that are unique to the agency operating the Medicaid and/or CHIP FFS program;

- A report on completed and ongoing state activities that evidence a good faith effort toward compliance; and
- A comprehensive plan to meet the requirements no later than 1 year after the compliance date.

Approval of an extension request will be based on whether the state sufficiently established the need to delay implementation and provided a comprehensive plan to comply with the requirements by the end of the extension period.

b. Exemptions

With respect to exemptions, CMS will permit state Medicaid FFS programs to request an exemption from the requirements of the Provider Access, Payer-to-Payer and/or Prior Authorization APIs when at least 90 percent of the state's Medicaid beneficiaries are enrolled in Medicaid MCOs. Similarly, separate CHIP FFS programs may apply for an exemption from the requirements for those APIs if at least 90 percent of the state's separate CHIP beneficiaries are enrolled in CHIP managed care entities. However, CMS also finalizes its proposal that the requirements for the Payer-to-Payer API to obtain beneficiaries' permission, provide educational resources at the time of requesting permission, and identify patients' previous/concurrent payers, including for beneficiaries covered under managed care, are not eligible for the exemption.

The rationale for these exemptions is that state time and resource investments necessary to implement the API requirements would likely outweigh the benefits of implementing the API. States granted an exemption would have to implement an alternative plan to enable the efficient electronic exchange and accessibility of PA information for those FFS beneficiaries to ensure that enrolled providers will have efficient electronic access to the same information available under APIs through other means.

An exemption request must be submitted in writing and include documentation that the state meets the criteria for the exemption based on enrollment data as well as information on alternative plans to ensure providers have efficient electronic access to the same information through other means while the exemption is in effect. Exemptions will be terminated under either of the following circumstances:

- Based on the 3 previous years of available, finalized Medicaid T-MSIS and/or CHIP CARTS managed care and FFS enrollment data, the state's managed care enrollment for 2 of the previous 3 years is below 90 percent; or
- CMS has approved a state plan amendment, waiver, or waiver amendment that would significantly reduce the share of beneficiaries enrolled in managed care and the anticipated shift in enrollment is confirmed by available, finalized Medicaid T-MSIS and/or CHIP CARTS managed care and FFS enrollment data.

For the first circumstance, the state must notify CMS that it no longer qualifies for the exemption because the state's managed care enrollment fell below the 90 percent threshold for 2 of the previous 3 years. For the second circumstance, the state must notify CMS that it no longer qualifies for the exemption when data confirm that there has been a shift from managed care enrollment to FFS enrollment as anticipated in the state plan amendment or waiver approval.

Under both circumstances, the notice must be submitted within 90 days of finalization of the first annual Medicaid T-MSIS managed care enrollment data and/or the CARTS report for CHIP confirming that there has been the requisite shift from managed care enrollment to FFS enrollment. If the exemption expires, the state must get CMS' approval of a compliance timeline for the requirements for the state's Medicaid FFS and/or CHIP FFS populations within two years of the expiration date of the exemption.

Additionally, for states with Medicaid expansion CHIPs, the requirements for Medicaid will apply to those programs rather than the provisions for separate CHIPs.

CMS did not propose an extension or exemption process for Medicaid and CHIP managed care because the agency assumes that these entities are already developing the requisite infrastructure to comply with the requirements.

Comments/Responses: Some commenters were concerned about the impact of extensions on Medicaid enrollees and on provider adoption of the necessary technology. CMS agrees that provider adoption of certain APIs, especially the Prior Authorization API, will be an important factor in achieving burden reduction. CMS cites its new Medicare Electronic Prior Authorization measures as one incentive for providers to adopt the Prior Authorization API. The agency also notes that while the extensions and exemptions apply to the new API provisions of this final rule, other finalized policies must still meet the compliance dates established in this rule, including the PA information to be included in the Patient Access API; information required under the finalized PA process, such as providing a specific reason for denial; and revised timeframes for issuing PA decisions.

One commenter opposed the exemption policy because they believe it creates a two-tiered system that may disproportionally impact people with disabilities who already face high barriers to care. CMS says it considered this possibility and notes that CMS will only grant a state an exemption from the API requirements if the state establishes an alternative plan that enables the electronic exchange and accessibility of the required information that would otherwise be shared through the API. Other commenters requested the same flexibility for additional payers and plan types. CMS responds that the narrow policy for state Medicaid and CHIP FFS programs is because they face certain unique challenges. For example, they do not have many discrete health care plans, and therefore cannot balance implementation costs across plans with low enrollment and those with higher enrollment. Additionally, states have complex procurement and staffing and/or recruitment challenges that do not apply to nongovernmental organizations. Some commenters noted that states may have established state-level policies that conflict with the API requirements; CMS responds that this final rule pre-empts any conflicting state law.

2. Exception for QHP Issuers

CMS finalizes its proposal to permit QHP issuers on the FFEs to request an exception to the requirements for the Provider Access, Payer-to-Payer and/or Prior Authorization APIs as part of its application for QHP certification to be offered through an FFE. That request must include a narrative justifying the reasons why the issuer could not satisfy the requirements for the applicable plan year, the impact of that non-compliance on providers and enrollees, the current or

proposed means of providing health information to providers, and solutions and a timeline to achieve compliance with those requirements.

FFEs will decide whether to grant or deny these exception requests. To grant a request for an exception, the FFE must determine that making the QHPs of the issuer available through such FFE is in the interests of qualified individuals in the state or states where the FFE operates, and an exception is warranted to allow the issuer to offer QHPs through the FFE.

3. Federal Funding for State Medicaid and CHIP Expenditures on Implementation of the Prior Authorization API

CMS discusses the potential for federal matching funds to support implementation of the Provider Access, Payer-to-Payer and/or Prior Authorization APIs. For Medicaid this could be the standard 50 percent matching rate under section 1903(a)(7) of the Act or higher rates for expenditures related to designing, developing and installing (DDI) of mechanized claims processing and information retrieval systems (90 percent) under section 1903(a)(3)(A)(i) of the Act or operating claims processing and information retrieval systems (75 percent) under section 1903(a)(3)(B) of the Act.

For CHIP agencies, section 2105(c)(2)(A) of the Act would limit administrative costs to no more than 10 percent of a state's total computable expenditures for a fiscal year for administrative claims for developing the APIs required under this rule. Additionally, the temporary Medicaid FMAP increase available under section 6008 of the Families First Coronavirus Response Act does not apply to administrative expenditures.

F. Electronic Prior Authorization Measures for MIPS Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

1. Overview

CMS finalizes, with several modifications, the addition of a new measure, the Electronic Prior Authorization measure, for MIPS eligible clinicians under the Promoting Interoperability (PI) performance category of MIPS, and for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program (PIP). The measure will be included in the Health Information Exchange (HIE) objective for both the MIPS PI performance category and for the Medicare PIP and is designed to address concerns over low provider utilization of APIs established by payers for electronic prior authorization. As finalized, MIPS eligible clinicians will be required to report the measure beginning with the 2027 performance period/2029 MIPS payment year (rather than the 2026 performance period/2028 MIPS payment year, as proposed), and eligible hospitals and CAHs will be required to report the measure beginning with the 2027 EHR reporting period (rather than the 2026 EHR reporting period, as proposed). Also, in response to comments and to reduce burden, the measure is finalized as an attestation (yes/no) measure rather than as a numerator/denominator measure.

2. Description of Proposed Measure

The following specifications had been proposed for the Electronic Prior Authorization measure:

For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period or 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 Prior Authorization API using data from certified electronic health record technology (CEHRT). The MIPS eligible clinician, eligible hospital, or CAH, as applicable, would be required to report a numerator and denominator for the measure or (if applicable) report an exclusion.

- Denominator. The number of unique prior authorizations requested for medical items and services (excluding drugs) ordered by the MIPS eligible clinician during the performance period or 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 Prior Authorization API because the payer does not offer an API that meets the Prior Authorization API requirements and
- Numerator. The number of unique prior authorizations in the denominator that are requested electronically from a Prior Authorization API using data from CEHRT.
- Exclusions. Any MIPS eligible clinician, eligible hospital, or CAH that:
  (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period or 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 Prior Authorization API requirements during the applicable performance period or EHR reporting period.

The Prior Authorization API would automate compilation of necessary data to populate the HIPAA-compliant prior authorization request. Additional information not contained in CEHRT may also be required for submission, and the information would then be packaged into a HIPAA-compliant transaction for transmission to the payer. The measure would not alter a covered entity's obligation to use the HIPAA transaction standards required under 45 CFR 162.1302.

If a MIPS eligible clinician, eligible hospital or CAH fails to report the measure or claim an exclusion, with respect to a performance period or reporting period, as the case may be, they would not satisfy the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program reporting requirements, respectively, for that performance or reporting period. For the proposed measure, if the MIPS eligible clinician, eligible hospital, or CAH does not report a numerator of at least one for the measure or claim an exclusion, they would receive a zero score for the MIPS PI performance category or the Medicare PIP, respectively.

3. Selected Comments/Responses

Several commenters opposed adoption of the Electronic Prior Authorization measure, believing that the measure would be inefficient and burdensome, citing challenges with additional workflow requirements, increased provider burden, and financial burden that would outweigh benefits. Commenters specifically expressed disapproval of the measure's numerator and denominator criteria because they would create significant data collection and reporting burden for both providers and health IT developers. CMS acknowledges the initial implementation and data collection burden, but believes that making the prior authorization process electronic will result in overall less burden than the current prior authorization process. The agency also recognizes the challenges of consistently calculating a numerator and denominator for the measure across providers if providers are accessing the Prior Authorization API in different ways, and further agrees there are challenges to report a numerator and denominator until such time as the ONC Health IT Certification Program establishes health IT certification criteria to support standardized exchange via the Prior Authorization API. To address these concerns, the agency is modifying the proposed measure to be an attestation (yes/no) measure, rather than a numerator and denominator measure.

A few commenters expressed concern about the potential adverse effect of the measure on small, rural, and underserved practices and populations. CMS responded by noting that there are circumstances for which MIPS eligible clinicians may qualify for reweighting of the MIPS Promoting Interoperability performance category, including if they have a special status (defined at 42 CFR 414.1305), are a qualifying clinician type, or have a CMS-approved significant hardship or other exception. The agency specifies that MIPS eligible clinicians in small practices (fifteen or fewer MIPS eligible clinicians) may have the MIPS PI performance category reassigned a weight of zero percent automatically if the MIPS eligible clinician in a small practice (as verified by CMS on an annual basis) does not submit any data for any of the measures in that category, and therefore would not be required to meet the category's requirements including reporting on this Electronic Prior Authorization measure.

Some commenters expressed that the agency should collect prior authorization data from payers to measure their performance rather than from providers. CMS responds that the success of the Prior Authorization API depends on both payers implementing it and providers using it. Requirements for payers to implement and maintain Prior Authorization API are in section II.D. of the final rule. The agency emphasizes that the policies finalized in the rule are not intended to discourage or encourage the use of prior authorization as a method to verify before an item or service is provided whether the item or service is medically necessary, meets coverage criteria, and is consistent with standards of care. The proposals under the rule are limited to streamlining the existing process.

Multiple commenters questioned how the measure aligns with the goals of MIPS and the Medicare PIP to improve the quality of health care. The agency believes that the measure supports care improvement by making a burdensome process more efficient so that providers can spend more time on patients instead of an administrative process. Specifically, CMS believes the measure is fundamental to determining whether a MIPS eligible clinician, eligible hospital, or CAH meets the second criterion of being a meaningful EHR user—that is, demonstrating that

their CEHRT is connected in a manner that provides for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.[31]

Some commenters expressed concerns that some providers may not have enough prior authorization requests or the necessary technology to support the costs of electronic prior authorization. CMS believes all affected providers would benefit from the use of electronic prior authorization and that the finalized policy, as modified, which requires reporting only "of at least one" medical item or service (excluding drugs) ordered during the performance period or "of at least one" discharge during the EHR reporting period is achievable for any provider who has more than zero prior authorization requests.

Multiple commenters opposed the measure because ONC has not established health IT certification criteria to ensure EHRs communicate with payers through the Prior Authorization API. CMS responds by signaling the agency's intent in this area, noting that the Unified Agenda includes an entry for a proposed rule from ONC (RIN 0955-AA06) with a description for proposals for the expanded use of certified APIs for electronic prior authorization,[32] and that the agency will work with ONC to ensure that any future updates to the ONC Health IT Certification Program around electronic prior authorization will improve health care providers' capabilities to interact with the Prior Authorization APIs established by payers. The agency further responds that providers can report on the measure, attesting "yes" they submitted an electronic prior authorization request using the Prior Authorization API with data from CEHRT, without needing further certification criterion in the ONC Health IT Certification Program.

4. Final Action: Measure Finalized with Modifications

CMS finalizes its proposal to add the Electronic Prior Authorization measure under the MIPS Promoting Interoperability performance category for MIPS eligible clinicians and the Medicare PIP for eligible hospitals and CAHs to incentivize use of the Prior Authorization API among providers, but with several modifications, most notably:

- MIPS eligible clinicians will be required to report the measure beginning with the 2027 performance period/2029 MIPS payment year (rather than the 2026 performance period/2028 MIPS payment year), and eligible hospitals and CAHs will be required to report the measure beginning with the 2027 EHR reporting period (rather than the 2026 EHR reporting period).
- To reduce burden, the measure is finalized as an attestation (yes/no) measure rather than as a numerator/denominator measure, as had been proposed. MIPS eligible clinicians, eligible hospitals, and CAHs will be required to report a "yes" or "no" response to having performed at least one electronic prior authorization through a Prior Authorization API using data from CEHRT during the applicable performance period or EHR reporting period, or report an applicable exclusion for the measure.

[31] Sections 1848(o)(2)(A)(ii) and 1886(n)(3)(A)(ii) of the Social Security Act.
[32] Office of Information and Regulatory Affairs (2023, November). Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability. Retrieved from https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202304&RIN=0955-AA06.

The measure will not be scored (that is, not assigned points for completion or failure). However, if a MIPS eligible clinician, eligible hospital, or CAH fails to report the measure, they will not meet the minimum reporting requirements. Only a "yes" response on the attestation, or claiming an applicable exclusion, will fulfill the minimum requirements of this measure. A "no" response will result in the MIPS eligible clinician, eligible hospital, or CAH failing to meet the measure. Failure to meet the measure means failure to meet minimum program reporting requirements, thus not being considered a meaningful EHR user, and receiving a zero score for the MIPS Promoting Interoperability performance category for the performance period or failing the Medicare Promoting Interoperability Program for the EHR reporting period.

- The failure in the Medicare Promoting Interoperability Program would result in a downward payment adjustment for eligible hospitals or CAHs (unless the eligible hospital or CAH receives a hardship exception).
- The failure in the Promoting Interoperability performance category means the MIPS eligible clinician will receive a score of zero for the performance category, which is currently worth 25 percent of their final score for MIPS.

The measure exclusion criteria are finalized as excluding MIPS eligible clinicians, eligible hospitals, and CAHs that only order medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the Prior Authorization API requirements finalized in the rule. Also, MIPS eligible clinicians, eligible hospitals, and CAHs that do not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period or EHR reporting period could claim an exclusion from the measure. CMS is not finalizing an exclusion based on any minimum number (other than zero) of prior authorization requests.

The following specifications are finalized for the Electronic Prior Authorization measure:

Measure Description for MIPS eligible clinicians under the MIPS PI Performance Category—Electronic Prior Authorization. For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically from a Prior Authorization API using data from CEHRT.

- Reporting requirement. The MIPS eligible clinician is required to report a yes/no response for the measure or (if applicable) report an exclusion. To successfully report this measure, MIPS eligible clinicians must attest "yes" to requesting prior authorization electronically via a Prior Authorization API using data from CEHRT for at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period or (if applicable) report an exclusion.
- Exclusions. Any MIPS eligible clinician who:
  (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance 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 Prior Authorization API requirements during the applicable performance period.

Measure Description for Eligible Hospitals and Critical Access Hospitals in the Medicare PIP—Electronic Prior Authorization. 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 Prior Authorization API using data from CEHRT.

- Reporting Requirement. The eligible hospital or CAH would be required to report a yes/no response for the measure or (if applicable) report an exclusion. To meet this measure, the eligible hospital or CAH must attest "yes" to requesting a prior authorization electronically via a Prior Authorization API using data from CEHRT for at least one hospital discharge and medical item or service (excluding drugs) ordered during the EHR reporting period or (if applicable) report an applicable exclusion.
- 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 Prior Authorization API requirements during the applicable EHR reporting period.

G. Interoperability Standards for APIs

In order to reduce complexity and provide clarity, CMS proposed modifications to the standards for APIs at 45 CFR 170.215 that apply to previously finalized API requirements. It also proposed changes to those standards tailored to each new set of API requirements. The language changes specified the use of each standard at 45 CFR 170.215 that would apply to a given set of API requirements at the sections of the regulations identified in Tables 8 and 9 in the proposed rule. Table 10 of the proposed rule summarized the standards applicable for each set of API requirements.

For example, to relieve payers from unnecessary development with respect to the standard at §170.215(a)(2) (currently the HL7 FHIR® US Core Implementation Guide STU 3.1.1 (US Core IG)), CMS proposed that a payer would only be required to use technology conformant with the US Core IG where applicable, that is, where there is a corresponding FHIR Resource in their functional API, pursuant to the data requirements for the API. If the FHIR Resource has been profiled by the US Core IG, then the payer must support the FHIR Resource according to the FHIR Resource Profile's "Structure Definition" as specified in that standard.

CMS acknowledged that several of the IGs recommended for use for the APIs in the proposed rule build on specific profiles within the US Core IG and that recommended IGs and subsequent versions of these IGs may use profiles in updated versions of the US Core IG. The agency noted that payers may use updated versions of the recommended IGs that rely on newer versions of the US Core IG, as long as those updated versions meet the requirements of its policies for the use of updated standards and align with the procedures established by ONC under the Standards Version Advance Process (SVAP).

1. Use of Updated Standards

As established in the CMS Interoperability and Patient Access final rule (85 FR 25510), payers implementing a Patient Access or Provider Directory API may use an updated version of a standard subject to certain conditions. An updated version of a standard may be used if—

- The updated version of the standard is required by other applicable law, or not prohibited under other applicable law, provided that:
    - for content and vocabulary standards that are not included at 45 CFR 170.213, the Secretary has not prohibited use of the updated version of a standard for purposes of the section in which the provision is located, or 45 CFR part 170; and
    - for standards at 45 CFR 170.213 and 170.215, ONC has approved the updated version for use in the ONC Health IT Certification Program; and
- The updated version does not disrupt an end user's ability to use a required API to access the data required for that API.

CMS proposed to extend the policy to allow the use of an updated version of a standard to the Provider Access API, Payer-to-Payer API, and Prior Authorization API. However, when using updated standards, a payer must continue to support connectivity for end users and may only use an updated version of the standard if it does not disrupt an end user's ability to access the data available through the API. CMS proposed to allow the use of updated standards, specifications, or IGs for each of the API requirements at the sections of the regulations identified in Table 9 of the proposed rule. Updated versions of standards at 45 CFR 170.213 and 170.215 could only be used if ONC has approved the updated version for use in the ONC Health IT Certification Program.

Since the publication of the proposed rule, ONC published the HTI-1 final rule, which reorganized the structure of 45 CFR 170.215 to delineate the purpose and scope more clearly for each type of standard or implementation specification (89 FR 1283). The HTI-1 final rule adopted updated versions of several standards at 45 CFR 170.215, including the following:

- Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) Release 4.0.1 at 45 CFR 170.215(a)(1) (HL7 FHIR);
- HL7 FHIR US Core IG Standard for Trial Use (STU) 3.1.1, which expires on January 1, 2026, at 45 CFR 170.215(b)(1)(i);
- HL7 FHIR US Core IG STU 6.1.0 at 45 CFR 170.215(b)(1)(ii) (US Core IG),
- HL7 SMART Application Launch Framework IG Release 1.0.0, which expires on January 1, 2026, at 45 CFR 170.215(c)(1);
- HL7 SMART App Launch IG Release 2.0.0 at 45 CFR 170.215(c)(2) (SMART App Launch IG);
- FHIR Bulk Data Access (Flat FHIR) IG (v1.0.0: STU 1) at 45 CFR 170.215(d)(1) (Bulk Data Access IG); and
- OpenID Connect Core 1.0, incorporating errata set 1 at 45 CFR 170.215(e)(1) (OpenID Connect Core).

2. Implementation Guides

With respect to IGs that support API requirements listed in the proposed rule, CMS had proposed in the December 2020 CMS Interoperability proposed rule requiring the use of FHIR IGs, including the CARIN IG for Blue Button®, HL7® FHIR® Da Vinci PDex IG, HL7® FHIR® Da Vinci PDex U.S. Drug Formulary IG, HL7® FHIR® Da Vinci PDex Plan Net IG, Da Vinci Coverage Requirements Discovery (CRD) IG, Documentation Templates and Rules (DTR) IG, and Prior Authorization Support (PAS) IG for this purpose. As noted earlier, that December 2020

CMS Interoperability proposed rule has been withdrawn and CMS declines to require the use of those standards. At this time, it only recommends their use, while acknowledging that it could limit interoperability. CMS proposed to require the use of API technology that conforms with the standards at 45 CFR 170.215 as applicable for each set of proposed API requirements.

3. Final Action

a. Comments/Responses

Commenters took different positions on whether (1) the FHIR standard and FHIR APIs should be mandated, (2) the standards are sufficiently mature, (3) more testing should be conducted, including in a variety of clinical settings, and (4) the technical implementation challenges argued against adopting the FHIR standard and APIs. Concern was also expressed that CMS viewed the FHIR standard as the sole solution to interoperability and patient data exchanges. Similar positions were taken with respect to the IGs for the FHIR standards, and commenters presented arguments on both sides of the question as to whether IGs should be required or recommended. CMS believes the primary components in the FHIR standard are mature. While the agency acknowledges that the FHIR resource profiles included in the IGs it recommends have varying levels of maturity, it nonetheless believes they are sufficiently mature for industry to start implementing them. It anticipates more solutions will be available in the marketplace before the 2027 compliance dates. CMS decided to recommend rather than require the IGs because they continue to evolve, but it may consider requiring them if they continue to mature. It also says it will collaborate with ONC and DaVinci on testing the APIs and will monitor and evaluate IG development.

A number of commenters suggested that CMS provide financial incentives for market suppliers, providers, and payers to participate in the testing and development of technical standards, IGs, and applicable processes. The agency lacks the statutory authority to do so, but it does conduct educational webinars on technical requirements.

Commenters largely supported the use of updated versions of standards and specifications for APIs. Several commenters recommended that CMS update the clinical data requirements to USCDI v2 or v3. ONC's HTI-1 final rule establishes a January 1, 2026, expiration date for USCDI v1 and adopts USCDI v3 at 45 CFR 170.213 thereafter, which will apply to the required content for the APIs finalized in this rule.

b. Finalized Policies

CMS finalizes its proposals for interoperability standards for the Patient Access, Provider Access, Provider Directory, Payer-to-Payer, and Prior Authorization APIs. Impacted payers will only be required to use the applicable standards and specifications identified as necessary for APIs. Those standards are listed as "required" in Table H3 (shown below). A modification to the proposal is finalized; CMS will incorporate the expiration dates that ONC adopted at 45 CFR 170.215(b)(1)(i) and (c)(1) into the standards after the publication of the proposed rule. The finalized requirements include any additional mandatory support requirements listed, such as for

both the SMART App Launch IG at 45 CFR 170.215(c) and Bulk Data Access IG at 45 CFR 170.215(d).

For the Prior Authorization API, CMS finalizes its proposal with modifications; it will not require OpenID Connect Core at 45 CFR 170.215(e).

CMS recommends specific IGs, listed as "recommended" in Table H3 (shown below), which payers are encouraged to use in addition to the required standards at 45 CFR 170.215. Updated standards, specifications, or IGs may be used for each of these APIs, subject to the following:

- The updated version of the standard is required by other applicable law; or
- The updated version of the standard:
    - is not prohibited under other applicable law,
    - has been approved by ONC for use in the ONC Health IT Certification Program, and
    - does not disrupt an end user's ability to access the data required to be available through the API.

Table H3: Required Standards and Recommended Implementation Guides To Support API Implementation

API	*Required* Standards*	*Recommended* Implementation Guides
Patient Access API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(c)(1) HL7 SMART Application Launch Framework IG Release 1.0.0.*** 45 CFR 170.215(e)(1) OpenID Connect Core 1.0, incorporating errata set 1	HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: http://hl7.org/fhir/us/carin-bb/history.html HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davincipdex/history.html HL7 FHIR Da Vinci - Payer Data Exchange (PDex) US Drug Formulary IG STU 2.0.1. URL: http://hl7.org/fhir/us/Davinci-drugformulary/history.html
Provider Access API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(c)(1) HL7 SMART Application Launch Framework IG Release 1.0.0.*** 45 CFR 170.215(d)(1) FHIR Bulk Data Access (Flat FHIR) IG (v1.0.0: STU 1)	HL7 FHIR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: http://hl7.org/fhir/us/carin-bb/history.html HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davincipdex/history.html 45 CFR 170.215(c)(2) HL7 SMART App Launch IG, Release 2.0.0 to support Backend Services Authorization. URL: https://hl7.org/fhir/smart-applaunch/STU2/backend-services.html
Provider Directory API**	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.***	HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net IG STU 1.1.0. URL: http://www.hl7.org/fhir/us/davinci-pdex-plannet/history.html
Payer-to-Payer API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.*** 45 CFR 170.215(d)(1) FHIR Bulk Data Access (Flat FHIR) IG (v1.0.0: STU 1)	HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: http://hl7.org/fhir/us/carin-bb/history.html HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davincipdex/history.html 45 CFR 170.215(c)(2) HL7 SMART App Launch IG, Release 2.0.0 to support Backend Services Authorization. URL: https://hl7.org/fhir/smart-applaunch/STU2/backend-services.html
Prior Authorization API	45 CFR 170.215(a)(1) HL7 FHIR Release 4.0.1 45 CFR 170.215(b)(1)(i) HL7 FHIR US Core IG STU 3.1.1.***	HL7 FHIR Da Vinci - Coverage Requirements Discovery (CRD) IG STU 2.0.1. URL: http://hl7.org/fhir/us/davinci-crd/history.html HL7 FHIR Da Vinci - Documentation Templates and Rules (DTR) IG STU 2.0.0. URL: http://hl7.org/fhir/us/davinci-dtr/history.html

API	*Required* Standards*	*Recommended* Implementation Guides
	45 CFR 170.215(c)(1) HL7 SMART Application Launch Framework IG Release 1.0.0.***	HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG STU 2.0.1. URL: http://hl7.org/fhir/us/davincipas/history.html

* CMS made modifications to the required standards listed in this table from what was originally listed in Table 10 of the proposed rule.
** CMS removed the references to 45 CFR 170.215(c) SMART App Launch IG and 45 CFR 170.215(e) OpenID Connect Core for the Provider Directory API that were mistakenly included in the proposed rule.
*** In the HTI-1 final rule, ONC finalized expiration dates for several of these required standards to indicate when a version of a standard may no longer be used (89 FR 1192). CMS intends to align with updated versions finalized at 45 CFR 170.215 through future rulemaking before the API compliance dates.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, CMS must provide 60-day notice in the *Federal Register* and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. HHS identifies provisions in the final rule for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995.

Overall, CMS has estimated that there are 365 impacted payers that would be affected by these policies. They are comprised of plans, entities, issuers, and state programs, including:

- 288 Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs;
- 56 states, territories, and U.S. commonwealths which operate FFS programs; and
- One state that operates its CHIP and Medicaid FFS programs separately.

Table J9 in the rule shows the total burden across all impacted payers is estimated to be $182 million in year 1 and year 2; $199 million in year 3, and $142 million for each subsequent year. Those cost estimates assume the following:

- Modified compliance dates for the policies in this final rule that require API development or enhancement, Medicare Promoting Interoperability Program, and MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year or CY 2027 EHR reporting period to give 3 years (36 months) for appropriate implementation activities.
- Maintenance costs for the three APIs are assumed to be 25 percent of total costs; these maintenance costs will be incurred in CY 2027 and subsequent years.
- Certain provisions will be effective in January 2026; thus, no costs are reflected from 2023 through 2025. However, for the building of the API systems, CMS assumes impacted payers will be performing these updates in CY 2024 through 2026 to be prepared for the CY 2027 compliance date.
- Labor costs in Table J9 are either BLS wages when a single staff member is involved or a weighted average representing a team effort, which is obtained by dividing the aggregate cost by the aggregate hours.

The burden estimate for reporting Patient Access API metrics to CMS is presented in Table J2, and it assumes this would be conducted in two major phases: implementation, including defining

requirements and system design and updates to generate and compile reports; and maintenance, which includes compilation and transmission of annual reports to CMS. The implementation costs for the first year are estimated to be $15,091 per impacted payer. Aggregate costs across all parent organizations are estimated to be $5.5 million. Ongoing maintenance could cost each organization about $3,013 per year for a total aggregated annual cost of $1,099,672.

The Provider Access API would require three major work phases: initial design, development and testing, and long-term support and maintenance. CMS summarizes its estimates of the costs of the first two phases in Table J3. CMS prepared three estimates (low, median, and high estimates) for the first two phases, and the estimates reflected in this paragraph are the median or "primary" estimates from Table J3. One-time implementation efforts for the first two phases are estimated to cost $270,045 per organization with an aggregate burden across 365 parent organizations of $98.6 million. Ongoing maintenance costs are expected to be about one-quarter of the one-time API costs or $67,508 per parent organization—for a total of $24.6 million across all 365 parent organizations.

The Prior Authorization API would require three major work phases as well. CMS summarizes its estimates of the costs of the first two phases in Table J4. CMS prepared three estimates (low, median, and high estimates) for the first two phases, and the estimates reflected in this paragraph are the median or "primary" estimates from Table J4. CMS estimates one-time implementation costs for the first two phases of $1,144,444 per organization with aggregate costs of $417.7 million across 365 parent organizations. Ongoing maintenance costs are expected to be about one-quarter of the one-time API costs or $286,116 per parent organization—for a total of $104.4 million across all 365 parent organizations.

The per entity cost shown in Table J5 for the modifications to the timelines for impacted payers to send prior authorization decisions is estimated to be $967 with a total burden of $353,028.

The requirement for public reporting of prior authorization metrics would require first-year implementation costs of an estimated $29,574 per organization with total costs across all 365 parent organizations of $10.8 million (see Table J6). For subsequent years, costs for each organization are estimated to average $9,038 with aggregate costs of $3.3 million.

Establishing the Payer-to-Payer API would require three work phases. CMS summarizes its estimates of the costs of the first two phases in Table J7. CMS prepared three estimates (low, median, and high estimates) for the first two phases, and the estimates reflected in this paragraph are the median or "primary" estimates from Table J7. For initial design and development, CMS estimates costs of $96,072 per organization for an aggregate across 365 parent organizations of $35.1 million. Ongoing maintenance costs are estimated to be $24,017 for each parent organization for an aggregate cost of $8.8 million.

MIPS eligible clinicians, eligible hospitals, and CAHs must report the Electronic Prior Authorization measure beginning with the CY 2027 performance period/2029 MIPS payment year. In the final rule, CMS structured the measure as an attestation instead of a numerator and denominator measure as originally proposed. Table J8 shows an estimated total cost of $1,740 for eligible hospitals and CAHs (4,500 hospitals and CAHs × ½ minute × $46.42 per hour) and

an estimated total cost of $21,186 for MIPS eligible clinicians (54,770 clinicians × ½ minute × $46.42 per hour).

IV. Regulatory Impact Analysis

CMS examined the impact of the rules as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, Executive Order 14094, entitled "Modernizing Regulatory Review", the Regulatory Flexibility Act (RFA), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995, Executive Order 13132 on Federalism, and the Congressional Review Act.

Executive Order 12866, as amended, requires agencies to provide a regulatory impact analysis for all major rules with economically significant effects ($200 million or more in any year). CMS estimates that the rule is economically significant and so has prepared a Regulatory Impact Analysis assessing the costs and benefits of the policies finalized in this rule.

The Regulatory Flexibility Act requires agencies to analyze whether a rule would have a significant impact on a substantial number of small businesses. CMS certifies that for impacted payers, the final rule does not have a significant economic impact on a significant number of small entities. CMS states that MAOs, state Medicaid managed care plans and CHIP managed care entities have their costs covered through capitation payments from the federal government or through state payments; therefore, there would be no significant burden of the new APIs. Few of the QHP issuers that would be impacted are small businesses.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately $177 million, and the final rule will not impose an unfunded mandate that would result in spending in any year in excess of that threshold for a state, local or tribal government.

The estimated one-time cost for review of the rule is an aggregate of $1.3 million for the following 500 entities: 365 parent organizations impacted by the rule, 32 members of the Relative Value Scale Update Committee (RUC), and an additional 100 entities CMS includes, such as pharmacy benefits managers and major advocacy groups.

Indirect Savings from Adoption of Prior Authorization Provisions by Health Care Providers. CMS believes that an indirect impact of the final rule will be savings from reduced administrative work associated with prior authorization protocols. CMS provides a quantitative analysis of the potential cost savings resulting from reduced administrative work, but because of limitations in the analysis and the uncertain assumptions used to develop the estimates it provides only illustrative savings. While CMS believes the savings could be significant, they are not included in the summary tables of the expected costs or benefits of the rule.

CMS expects that an increasing percentage of providers will participate in electronic prior authorization such that by 2036, 50 percent of all providers will participate. The burden associated with the existing prior authorization process is estimated to be $48,882 per individual and group physician practice per year. CMS assumes there are total of 199,543 individual and group physician practices, of which the MIPS eligible clinician practices affected by this final rule are a subset. It also assumes that all the 54,770 MIPS eligible clinicians meet the requirements of this rule in 2027 since there are payment consequences for them not doing so; the number of MIPS eligible clinicians is expected to grow to 99,772 by 2036.

CMS believes the Prior Authorization API will make it possible for staff to use one system (such as their EHR or practice management system) or software application to find the prior authorization rules and documentation requirements for most impacted payers, compile the necessary data elements to populate the transaction, and provide the requisite documentation. Thus, it anticipates a reduction in prior authorization burden. CMS estimates physicians would reduce their time by 10 percent, registered nurses would have a reduction of 50 percent, and clerical staff would reduce their time by 25 percent. CMS estimates total savings of $15.8 billion in savings over the course of 10 years, as shown in Table K6. Adding hospital burden reductions to the estimate results in total estimated savings of at least $16.5 billion over a 10-year period.

Total Costs of Final Rule. Overall, Table K9 shows that the total estimated costs of the final rule (excluding premium tax credit payments and savings from prior authorization) could range from $0.8 billion to $2.3 billion.

Table K10 describes ways for payers to defray some of the costs of the final rule. For example, CMS notes that states may request extensions or exemptions from some of the API provisions and that QHPs could absorb the costs or request an exception because they are a small commercial QHP issuer on the FFE. MAOs would address the reduced rebates in their bids (arising from increased bid costs due to the increased costs of the final rule being included in the bid) by (1) temporarily absorbing costs by reducing profit margins; (2) reducing supplemental benefits paid for by the rebates; or (3) raising enrollee cost sharing (or reduce additional, rebate-funded benefits). CMS believes many MA plans, for competitive reasons, would choose to retain a zero-dollar premium increase and either absorb losses for 1 year or reduce rebate-funded supplemental benefits.

Alternatives Considered. CMS considered alternatives to the finalized requirements, including the following:

- As an alternative to the update to the Patient Access API, allowing patients and providers to upload patient data directly to a patient portal operated by a provider. Because patient portals are not sufficiently widespread and do not lend well to interoperability, CMS declined to pursue this alternative. In addition, CMS considered alternative compliance dates as well as requiring more frequent reports of Patient Access API metrics.
- Alternative data types that could be exchanged via the Provider Access API as well as including additional data elements.
- An enhanced Payer-to-Payer Data Exchange standard was considered as well as allowing a payer to share data without requiring the use of an API, but CMS determined it was most advantageous for payers to leverage an API for this enhanced data exchange. With

respect to the data elements, CMS considered requiring only the exchange of clinical data, but determined that including claims and encounter data would allow for better care coordination and more efficient payer operations.

- A phased approach was considered for the implementation of the Prior Authorization API, but CMS believes that it is less burdensome to require payers to populate these requirements for all items and services at the same time. CMS also considered, as an interim step, requiring payers to post on a public website the items and services for which prior authorization is required and their associated documentation rules, but it determined that this would not provide any reduced burden on payers or providers. CMS considered a phased timeline for implementation. It examined using only the X12 278 HIPAA transaction standard rather than requiring the implementation of a FHIR API to support the Prior Authorization API, but it decided the X12 278 standard did not have the functionality of the FHIR standard or IGs to support the requirements of the Prior Authorization API.
- CMS also considered several alternative timeframe policies for the completion of prior authorization decisions, but concerns were raised over the feasibility of implementing shorter timeframes.
- More frequent reporting of prior authorization metrics was also considered, but CMS concluded that its final policy decision is sufficient.