



## CMS Advancing Interoperability and Improving Prior Authorization Processes Final Rule

On January 17, 2024, CMS released the [Advancing Interoperability and Improving Prior Authorization Processes final rule](#), which applies to MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHPs on FFEs. This final CMS rule overall aims to improve patient, physician, and payer access to interoperable patient data and reduce the burden of prior authorization processes. Specifically, it includes provisions to improve prior authorization processes through policies and technology to enhance communication between patients, physicians, and payers.

### Table of Contents

- A. Patient Access API (section II.A)..... 1
- B. Provider Access API (section II.B)..... 7
- C. Provider Access API in Medicaid and CHIP (section II.B.5) ..... 13
- D. Payer to Payer Data Exchange on FHIR (section II.C) ..... 14
- E. Extensions, Exemptions and Exceptions (section II.C.5) ..... 24
- F. Improving Prior Authorization Processes (section II.D) ..... 36
- G. Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program (section II.E) ..... 42
- H. Interoperability Standards for APIs ..... 44

### A. Patient Access API (section II.A)

#### I. Prior Authorization Information

#### Finalized Changes

CMS is finalizing 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. CMS has modified this change and will not require payers to share the quantity of items or services used under a prior authorization or unstructured documentation related to a prior authorization, as discussed elsewhere in this final rule. CMS is also finalizing compliance dates of January 1, 2027—a year later than originally proposed for all entities affected.

CMS is finalizing its proposal to require impacted payers to make available generally the same information about prior authorization requests and decisions via the Provider Access and Payer-to-Payer APIs.

CMS is finalizing a requirement that the Patient Access API must include structured administrative and clinical documentation submitted by a provider related to the prior authorization request. Structured documentation includes any data received from a provider and stored in the payer's system in a standardized format with defined data attributes, such as USCDI or FHIR.

CMS is finalizing a requirement that impacted payers must make available any documentation that a provider sends to the payer to support a prior authorization request that is received in a structured format.

CMS is finalizing its proposed timeframe and requiring payers to make prior authorization information available via the Patient Access API within 1 business day of receiving a request. Impacted payers must update prior authorization information made available via the Patient Access API within 1 business day of any status change.

CMS is also finalizing its proposal requiring prior authorization data to be available via the Patient Access API for 1 year.

CMS is finalizing its proposal to require impacted payers to implement and maintain a Provider Access API that is consistent with the technical standards finalized in the CMS Interoperability and Patient Access final rule (85 FR 25558), including the Health Level Seven (HL7®) International Fast Healthcare Interoperability Resources (FHIR®) standard.

## **Background/Rationale**



Patients tend to receive care from multiple providers, leading to fragmented patient health records where various pieces of an individual's record are locked in disparate, siloed data systems. With patient data scattered across these disconnected systems, it can be challenging for providers to get a clear picture of the patient's care history, and patients may forget or be unable to provide critical information to their providers. This lack of comprehensive patient data can impede care coordination efforts and access to appropriate care. CMS believes that making available digital tools, 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. Making health information similarly available and interoperable broadens patients' options for accessing their records. While many patients may be satisfied using their payer's portal, using proprietary systems and data formats has led to a health care system where patient data are fragmented and often difficult to exchange between parties. Entities such as HIEs, health apps, and TEFCA Participants and Sub participants 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. Advances in nationwide data sharing, such as payers' Patient Access APIs, connections across HIEs, and exchange enabled by TEFCA, can facilitate secure and reliable access to these data sources. That is the reason that CMS and HHS are invested in establishing open standards and requirements for payers and providers to use standardized technology. While many patients are most familiar with their payer's portal, until the Patient Access API provisions went into effect on January 1, 2021, their options may have been limited.

CMS understands that payers currently support a variety of modalities for providers to submit prior authorization requests, including online portals, phone, and fax. However, CMS believes that patients should have access to their prior authorization data within the same timeframe, regardless of how the prior authorization request was submitted.

### **Comments**

A significant number of commenters expressed support for CMS' intention to ensure that Medicare FFS will comply with the requirements of this final rule by the compliance dates CMS is establishing. CMS did not make any policy proposals



regarding this effort but is considering comments as they plan their roadmap for implementation.

## **II. Patient Access API Metrics**

### **Finalized Changes**

CMS is finalizing the following patient access API Metrics:

1. The total number of unique patients whose data are transferred via the Patient Access API to a health app designated by the patient; and
2. 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.

CMS is finalizing the proposal to revise the description of the clinical data impacted payers must make available via the Patient Access API.

CMS is finalizing the proposal to specify that the data that payers must make available are “all data classes and data elements included in a content standard at 45 CFR 170.213.”

CMS is also finalizing its proposal to revise the language previously finalized for the denial or discontinuation of a health app’s access to the API.

CMS is also finalizing the proposal requiring impacted payers to annually report to CMS certain metrics about patient data requests made via the Patient Access API—starting January 1, 2026. CMS is also finalizing its proposal to directly reference the content standard at 45 CFR 170.213 so that the data content requirement is automatically updated as HHS’s Office of the National Coordinator for Health Information Technology (ONC) adopts new versions.

### **Background/Rationale**

CMS proposed to require impacted payers to report metrics to CMS on an annual basis about how patients use the Patient Access API in the form of aggregated, de-identified data. CMS stated that those reports would help them better understand whether the Patient Access API requirement is efficiently and effectively ensuring that patients have access to their health information and whether payers are providing that required information in a transparent and timely way. Additionally, CMS stated



that aggregated usage data from every impacted payer would help us evaluate whether the Patient Access API policies are achieving the desired goals. Furthermore, gathering this information would help CMS to provide targeted support or guidance to impacted payers, if needed, to help ensure that patients have access to their data and can use their data consistently across the impacted payer types.

## **Patient Access API Amendments**

### **Finalized Changes**

CMS is finalizing its proposal requiring impacted payers to make information about prior authorization requests and decisions available via the Patient Access API beginning in 2027 (by January 1, 2027, for MA organizations and state Medicaid and CHIP FFS programs; by the rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027 for QHP issuers on the FFEs), rather than in 2026.

CMS is also finalizing a requirement that, beginning 2027 (by January 1, 2027, for MA organizations and state Medicaid and CHIP FFS programs, by the rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027 for QHP issuers on the FFEs), impacted payers must make all of following information available about prior authorization requests and decisions (excluding for drugs) available via the Patient Access API:

1. The prior authorization status.
2. The date the prior authorization was approved or denied.
3. The date or circumstance under which the prior authorization ends.
4. The items and services approved.
5. If denied, a specific reason why the request was denied.
6. Related structured administrative and clinical documentation submitted by a provider.

CMS is also finalizing the requirement that impacted payers make this information about prior authorizations available no later than 1 business day after the payer receives a prior authorization request and must update that information no later than 1 business day after any status change. This information must be available for



the duration that the authorization is active and at least 1 year after the prior authorization's last status change.

CMS is finalizing a requirement that beginning in 2026, impacted payers must annually report Patient Access API metrics to CMS in the form of aggregated, de-identified data. Specifically, by March 31, MA organizations at the contract level, state Medicaid and CHIP FFS programs, Medicaid managed care plans and CHIP managed care entities at the state level, and QHP issuers on the FFEs at the issuer level must report the following metrics: (1)

1. the total number of unique patients whose data are transferred via the Patient Access API to a health app designated by the patient; and (2)
2. 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. I

CMS is finalizing its proposed rule, as of the effective date of this final rule, the replacement of "clinical data, including laboratory results" with "all data classes and data elements included in a content standard at 45 CFR 170.213" in the required content for the Patient Access API.

### **Background/Rationale**

CMS believes that giving patients access to their own health information can make them a more active participant in ensuring they receive timely and appropriate care (for example, allowing them to monitor medications or access treatment history). The finalized requirement to make information about prior authorization requests and associated documentation available through the Patient Access API is expected to allow beneficiaries to obtain information more easily about the status of prior authorization requests submitted on their behalf. Beneficiaries could potentially use that information to make more informed decisions about their health care, improve the efficiency of accessing and scheduling services, and, if needed, provide missing information that the state (or Medicaid managed care plan, if applicable) needs to reach a decision. Receiving missing information more quickly could enable more prompt responses from state Medicaid FFS programs, and Medicaid managed care plans to prior authorization requests, thus facilitating more timely and successful prior authorizations. This would help states fulfill their obligations to provide care and



services in a manner consistent with the simplicity of administration and the best interests of the recipients and to furnish services with reasonable promptness to all eligible individuals. Improving the prior authorization process could also help improve the efficient operation of the state plan by potentially improving the speed and consistency of prior authorizations, which could, in turn, facilitate faster access to care for beneficiaries.

These final policies apply to MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs.

## **B. Provider Access API (section II.B)**

### **I. Proposed Requirements for Payers: Provider Access API for Individual Patient Information**

#### **Finalized Changes**

CMS finalized their proposal to require impacted payers to implement and maintain a Provider Access API that is conformant with certain technical standards, documentation requirements, and denial or discontinuation policies beginning 2027. Specifically, those technical standards are HL7 FHIR at 45 CFR 170.215(a)(1), US Core IG at 45 CFR 170.215(b)(1)(i), SMART App Launch IG at 45 CFR 170.215(c)(1) and Bulk Data Access IG at 45 CFR 170.215(d)(1). Impacted payers are not required to use OpenID Connect Core. CMS also recommended payers use the CARIN IG for Blue Button STU 2.0.0, PDex IG STU 2.0.0, and SMART App Launch IG Release 2.0.0 to support Backend Services Authorization.

CMS finalized their proposal that impacted payers must make available to providers, via the Provider Access API, claims and encounter data (without provider remittances and patient cost-sharing information), all data classes and data elements included in a content standard at 45 CFR 170.213, and certain information about prior authorizations (excluding those for drugs) no later than 1 business day after receiving a request from a provider. CMS finalized a modification to their proposal and did not require payers to share the quantity of items or services used



under a prior authorization or unstructured documentation prior to a prior authorization.

### **Background/Rationale**

In the final rule, CMS required impacted payers to implement a Patient Access API that allows patients to access their health information through a third-party app. In the proposed rule, CMS sought comment on the feasibility of implementing and maintaining a FHIR API for data exchange between payers and providers and received comments strongly supporting their concept to require data availability through a Provider Access API. CMS agreed with commenters that making available information about prior authorization decisions via an API would reduce burden on providers and their staff. They also discussed the potential benefits of payers sharing patient health information directly with providers and encouraged payers to consider an API solution that would enable direct patient access to appropriate health information to support the delivery of care.

Further, CMS proposed to require impacted payers to implement and maintain a FHIR API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient. CMS also proposed a patient opt out, rather than an opt in policy that would require payers to allow patients to opt out of the Provider Access API. Finally, they proposed Provider Access API compliance dates in 2026.

In the proposed rule, CMS required impacted payers make certain health information through a Patient Access API when requested by a patient. Specifically, they proposed to require impacted payers make available any of the application patient data with a date of service on or after January 1, 2026 that they maintain. CMS proposed that payers would be required to make available via the Patient Access and Provider Access APIs information related to prior authorization requests and decisions for items and services (excluding drugs).

CMS decided to finalize their proposal to require impacted payers make available to providers, via the Provider Access API, claims and encounter data (without provider remittances and patient cost-sharing information), all data classes and data elements included in a content standard at 45 CFR 170.213, and certain information





about prior authorizations (excluding those for drugs). However, they finalized a modification to their proposal and are not requiring payers to share the quantity of items or services used under a prior authorization or unstructured documentation related to a prior authorization.

After considering public comments, CMS decided to finalize a 1 year delay in the compliance dates, to 2027 for each of the policies that require API development and enhancement. CMS notes that while making data related to prior authorizations available to providers is necessary and urgent, they understand that the finalized policies will take time for payers to implement. The additional year will give payers time for a smooth rollout of the new API as well as to onboard their providers. Since they are delaying the compliance dates, CMS does not believe a phased implementation is necessary and emphasizes that the compliance dates are only a deadline, and payers can meet the requirements as soon as possible.

Multiple comments supported CMS's proposal to require impacted payers to develop and maintain a Provider Access API and recommended CMS finalize the proposal. Multiple comments also noted that the API would give health care providers invaluable insights into patient care, which could lead to better quality care, reduce duplicate services, and streamline provider workflows. Multiple commenters supported the proposed 2026 compliance dates for the Provider Access API and some commenters supported earlier dates in calendar years 2024 and 2025, while some commenters requested CMS delay the implementation of the Provider Access API, to allow payers and providers the opportunity to stagger the separate implementation of the HIPPA Standards for Health Care Attachment proposed rule.

Multiple commenters requested clarification of "providers" that are eligible to use the Provider Access API as well as how CMS defines a payer's network.

Multiple commenters cautioned that this rule puts a large burden on payers with little burden on providers and that given the number of resources needed to implement the API, provider uptake is critical. CMS emphasized that the technical requirements for the Provider Access API align almost identically with those already established for the Patient Access API that impacted payers are required to maintain.



Multiple commenters recommended CMS streamline the proposed required data to limit duplicate information and overwhelmed providers, however, some commenters suggested additional data should be made available via the Provider Access API.

## **II. Additional Proposed Requirements for the Provider Access API**

### **a. Attribution**

CMS finalized their proposal as proposed that impacted payers must 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.

### **b. Opt Out**

CMS finalized their proposal as proposed that all impacted payers must establish and maintain a process for patients or their representatives to opt out of data exchange via the Provider Access API, or to tap back in after opting out beginning January 1, 2026.

### **c. Patient Educational Resources Regarding the Provider Access API**

CMS finalized their proposal that impacted payers provide educational resources in plain language to their patients about the Provider Access API. Those resources must include information about the benefits of API data exchange, opt out rights, and instructions for opting out and opting in, and this information must be made available to patients before the first date on which the payer makes their information available via the Provider Access API, no later than one week after the start of coverage. Start of coverage is defined differently, as applicable, for each type of impacted payer.

### **d. Provider Resources Regarding the Provider Access API**

CMS finalized their proposal that impacted payers are required to develop resources for providers about the Provider Access API in plain language.

## **Background/Rationale**

### **a. Attribution**



CMS proposed to require impacted payers to maintain an attribution process to associate patients with their in-network or enrolled (as applicable) providers to ensure that a payer only sends a patient's data to providers who have a treatment relationship with that patient. They note that the process of attribution can relate to many payer functions, including managing contracts, payments, financial reconciliation, reporting, and continuity of care. CMS shares that they did not propose a prescription attribution process in order to provide payers the flexibility to use systems and processes they already have in place, where appropriate, or to develop new policies and procedures to ensure that access to a patient's data through the Provider Access API is limited to providers who have a treatment relationship with the patient.

Multiple commenters expressed their support for CMS's proposed requirement that impacted payers maintain a process to verify a provider-patient relationship and to ensure data is shared appropriately to do so. Many commenters urged CMS to align patient attribution requirements and processes across payer types and leverage the CMS Innovation Center to identify where the process can be streamlined. Some commenters requested CMS take into account the additional burdens of the attribution process for providers who may only see a patient once; CMS underscored that they do not intend to overburden providers or their staff with the attribution process and reiterate that they believe payers can attribute most patients to providers via claims.

b. Opt Out

CMS proposed an opt out approach because opt in models of data sharing have been shown to inhibit the utilization and usefulness of data sharing efforts between patients and health care providers. They acknowledge that there are positives and negatives to both opt in and opt out policies, and that some patients may prefer to control or direct their health information via an opt in process, however, patients who have less health literacy may be less likely to use the Patient Access API, so having an opt out policy for Provider Access API would facilitate sharing data directly with the provider, without requiring action by the patient. In addition, CMS underscores their belief that data sharing as a default option for all patients can enhance both personal and organizational health literacy.

Multiple commenters expressed support for the proposed policy, highlighting the fact that the opt out framework would enable patients to protect and control their health information while still making patient data available to providers, encourage increased data transmission, and allow patients to terminate a provider's access to their data when the patient no longer has a treatment relationship with the provider. Multiple comments noted that an opt out approach is less burdensome for payer, while an opt in approach would require patients to have a higher level of education and health literacy, which may result in fewer patients having their data exchanged via the Provider Access API.

c. Patient Educational Resources Regarding the Provider Access API

To help patients understand the implications of the opt out provision for the Provider Access API, CMS proposed to require impacted payers to disseminate certain educational resources to their patients. They proposed that these resources would include information about the benefits to the patient of API data exchange, their opt out rights, and instructions for opting out of the data exchange and for opting in after previously opting out. CMS proposed that payers would have to provide this information, in non-technical, simple, and easy-to-understand language, before the first date on which the payer makes patient information available through the Provider Access API, at the time of enrollment and annual thereafter. They also proposed that payers would be required to make this information available at all times, in an easily accessible location on payers' public websites. CMS believes it is important to honor patient privacy preferences and provide patients with educational resources about their right to opt out of the Provider Access API data sharing.

Multiple commenters supported the proposed requirement for payers to disseminate patient educational resources, whether that be through existing patient portals, letters, text messages, websites, or by mail. CMS decided to include a modification regarding payer deadlines to give payers more clarity and an appropriate amount of time to meet requirements. The one-week timeframe is intended to provide a reasonable amount of time after a payer receives confirmation that a patient will be enrolled in coverage with them. CMS's proposed language included the patient education resources be in "non-technical, simple, and in easy-to-understand

language,” but their finalized requirement is that providers use “plain language.” CMS made this change to highlight that they encourage impacted payers to follow the federal government’s plain language guidelines.

d. Provider Resources Regarding the Provider Access API

CMS proposed to require impacted payers to develop non-technical and easy-to-understand resources for providers about the Provider Access API. They proposed that these resources would have to include information about the process for requesting patient data from payers via the Provider Access API and how to use the payer’s attribution process to associate patients with the provider. CMS proposed that impacted payers provide these resources to providers through the payer’s website and other appropriate provider communications. CMS opted to modify the language of the final rule to instead, clarify that provider resources be in plain language.

Multiple commenters expressed support for requiring impacted payers to make these resources readily available, while some commenters highlighted that it is unreasonable for a provider and their staff to access each payers’ website to obtain the payers’ specific resources. To be consistent with their revision to the patient education resources policy, CMS decided to finalize the text to require provider education resources in “plain language,” as opposed to their proposed, “non-technical, simple, and in easy-to-understand language.”

## **C. Provider Access API in Medicaid and CHIP (section II.B.5)**

### **I. Federal Funding for State Medicaid and CHIP Expenditures on Implementation of the Provider Access API**

#### **Finalized Changes**

#### **Background/Rationale**

This section does not include a final proposal. In responses to comments regarding whether enhanced FFP is available to implement patient access requirements, CMS clarifies that states may be eligible for enhanced FFP for the implementation of various APIs. Enhanced FFP may also be available for Patient Access API

requirements. States are encouraged to seek 90% enhanced FFP for API implementation costs, and CMS encourages states to submit APDs for review.

Regarding comments on funding resources available to states to expand the number of SNF providers able to utilize the new provider access API, CMS indicates that states can use Federal funding for the implementation of the Prior Authorization API, including pass-through payments to providers for interoperable Electronic Health Record (EHR) technology. However, CMS notes that enhanced Federal Medicaid funding is specifically available for state expenditures on Medicaid state systems and not for other state or provider expenditures.

## **II. Medicaid Expansion CHIP Program**

### **Finalized Changes**

At 42 CFR 457.700(c), CMS finalized the proposal which stipulates that the requirements proposed and finalized for Medicaid will be applicable to Medicaid Expansion CHIP programs. Specifically, the Medicaid requirements outlined in §§ 431.60, 431.61, and 431.80 will apply to Medicaid expansion CHIP programs, replacing the separate CHIP requirements at §§ 457.730, 457.731, and 457.732.

### **Background/Rationale**

CMS clarifies that Medicaid requirements apply equally to Medicaid expansion CHIP programs, noting that this change aligns and integrates the regulatory framework for Medicaid Expansion CHIP programs with the established Medicaid requirements rather than maintaining distinct provisions for CHIP.

### **Comments (if applicable)**

## **D. Payer to Payer Data Exchange on FHIR (section II.C)**

### **I. Proposal to Rescind the CMS Interoperability and Patient Access Final Rule Payer to Payer Data Exchange Policy (section II.C.2)**

### **Finalized Changes**



CMS finalized to rescind the payer-to-payer data exchange policy previously finalized in the CMS Interoperability and Patient Access rule. In its place, CMS finalized a new Payer-to-Payer API using the FHIR standard.

CMS also corrected a technical error in this final rule – by clarifying that NEMT PAHPs do not need to implement and maintain a Payer-to-Payer API.

### **Background/Rationale**

CMS wanted to rescind the previous policy to prevent industry from developing multiple systems and to help payers avoid the costs of developing non-standardized, non-API systems, and associated challenges. Using FHIR APIs would ensure greater uniformity and ultimately lead to payers having more complete information available to share with patients and providers.

Commenters supported CMS' proposal, agreeing that it would help standardize data exchange and avoid duplicative systems. They also supported the new FHIR API approach.

## **II. Payer to Payer Data Exchange on FHIR (section II.C.3)**

### **Finalized Changes**

- Payer-to-Payer API Technical Standards

CMS finalized that beginning in 2027, impacted payers must implement and maintain a Payer-to-Payer API that is compliant with the same technical standards, documentation requirements, and denial or discontinuation of policies as the current Patient Access API requirements. CMS finalized with modification its proposals for the Payer-to-Payer API to use the following standards: HL7 FHIR Release 4.0.1 at 45 CFR 170.215(a)(1), US Core IG at 45 CFR 170.215(b)(1)(i), and Bulk Data Access IG at 45 CFR 170.215(d)(1). CMS also recommended payers use the CARIN IG for Blue Button STU 2.0.0, PDex IG STU 2.0.0, and SMART App Launch IG Release 2.0.0 to support Backend Services Authorization. CMS is not finalizing a requirement for impacted payers to use SMART App Launch IG and OpenID Connect Core.

These technical specification requirements for the Payer-to-Payer API apply to MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFE.



While previously requirements were to be enforced on January 1, 2026, CMS is extending the compliance date to 2027.

- Payer-to-Payer API Data Content Requirements

CMS finalized its proposals with modifications. CMS decided to exclude data related to denied prior authorizations. In addition, they are also finalizing a modification by only requiring impacted payers to exchange data with a date of service within 5 years of the request.

Thus, CMS finalized its proposal that impacted payers must implement and maintain a FHIR Payer-to-Payer API to exchange all data classes and data elements included in a content standard, claims and encounter data, and prior authorization requests and decisions that the payer maintains with a date of service within 5 years of the request. This would include the status of the prior authorization, the date the prior authorization was approved or denied, the date or circumstance under which the prior authorization ends, the items and services approved, and the quantity used to date. However, it would no longer include data related to denied prior authorizations.

CMS finalized several other modifications to the information requirements under the Payer-to-Payer API. CMS finalized a modification that will not require payers to share the number of items or services used under a prior authorization. CMS also finalized a modification that this information does not need to be included in the Patient Access API or the Provider Access API.

CMS also finalized excluding provider remittances and patient cost-sharing information from the Payer-to-Payer API because that information is often considered proprietary by payers.

- Identifying Previous and Concurrent Payers and Opt In

CMS finalized its requirement for payers to maintain a process to identify a new patient's previous and/or concurrent payer(s) to facilitate data exchange using the Payer-to-Payer API. Impacted payers would be required to allow a patient to report multiple previous and/or concurrent payers if they had concurrent coverage. CMS is finalizing a modification to the proposal to establish a deadline for these processes at 1 week after the start of coverage, with certain differences among payers. For MA organizations, the deadline is no later than 1 week after the coverage start date or no





later than 1 week after receiving acceptance of enrollment from CMS, whichever is later. In the case of Medicaid and CHIP FFS, both deadlines now refer to 1 week after enrollment, to avoid confusion related to the retroactive eligibility rules in Medicaid. For QHP issuers on the FFEs, they are modifying the requirement to no later than 1 week after the after the coverage start date or no later than 1 week after the effectuation of coverage, whichever is later.

CMS also finalized that impacted payers would be required to establish similar processes for current patients prior to the compliance dates, to ensure those patients have the ability to opt in and have their data shared through the API.

CMS finalized an opt in approach for the data exchange through the Payer-to-Payer API. This opt in requirement does not apply to data exchanges between a state Medicaid or CHIP program and its contracted managed care plans or entities.

- Requesting Data Exchange from a Patient's Previous/Concurrent Payer(s) and Responding to such a Request

CMS finalized a requirement that payers must request a patient's data from their previous and/or concurrent payer(s) through the Payer-to-Payer API, no later than 1 week after the start of coverage. Impacted payers should be required to include the attestation with the request for data affirming that the patient has enrolled with that requesting payer and has opted in to the data exchange.

If an impacted payer receives a request from another payer to make data available for former patients who have enrolled with the new payer or a current patient who has concurrent coverage, CMS finalized requiring the impacted payer to respond by making the required data available via the Payer-to-Payer API within 1 business day of receiving the request. These payer-to-payer data exchange timeframe requirements will apply to MA organizations, state Medicaid and CHIP FFS agencies, and QHP issuers on the FFEs.

CMS is also finalizing a modification 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.

- Ongoing Data Exchange Requirements for Concurrent Coverage



CMS finalized that impacted payers would be required, within 1 week of the start of a new patient's coverage, to request initial data exchange from any concurrent payers that the patient reports. When a patient has concurrent coverage with two or more payers, the impacted payers must exchange the patient's data available to every other concurrent payer at least quarterly. After an impacted payer receives a request for a current patient's data, the receiving payer must respond with the appropriate data within 1 business day of receiving the request. CMS also finalized that any impacted payer that receives patient data from another payer under these regulations must incorporate those data into the recipient payer's records about the patient.

CMS finalized a modification to its proposal to allow concurrent payers to agree to exclude from ongoing quarterly data exchange any data that were previously transferred to or originally received from the other concurrent payer.

CMS highlights that if a non-impacted concurrent payer does not have the capability or refuses to exchange the required data with an impacted concurrent payer through FHIR API, the impacted payer is not required to exchange data with that non-impacted payer and request data exchange quarterly.

- Data Incorporation and Maintenance

CMS finalized that any information received by an impacted payer through this data exchange 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.

CMS chose to not require impacted payers to maintain data for unenrolled patients any longer or differently than they do today under current law, regulation, or policy.

- Patient Education Resources

CMS finalized impacted payers to provide educational materials regarding the payer-to-payer data exchange at least annually to all patients at or before requesting opt in. At a minimum, payers will have to explain: the benefits of the Payer-to-Payer API data exchange, patients' ability to opt in or withdraw their permission, and instructions for doing so. Impacted payers will be required to provide

these educational resources to patients at or before requesting permission for the Payer-to-Payer API data exchange. CMS finalized a modification for the information to be provided in “plain language” rather than the phrase “non-technical, simple, and easy-to-understand language.”

As discussed previously, currently enrolled patients must be given the opportunity to opt into the payer-to-payer data exchange and to provide previous/concurrent payer information before the API compliance dates. CMS finalized that impacted payers would be required to provide these educational resources to those currently enrolled patients at or before requesting their opt in as well.

In addition, CMS finalized that similar resources would have to be provided annually to all covered patients in mechanisms that the payer regularly uses to communicate with patients. Impacted payers would also be required to post these resources in an easily accessible location on the payer’s public website.

Because the Payer-to-Payer API compliance dates are moving to 2027, this requirement to providing educational resources is also moving to 2027.

### **Background/Rationale**

- Payer-to-Payer API Technical Standards

Multiple commenters stated their support for the proposed FHIR standard and recommended IGs for the Payer-to-Payer API. They stated that the FHIR standard will ultimately prevent issues with data sharing across payers and allow information to be shared accurately and timely. Some commenters noted that the standard has not been widely demonstrated in production by industry stakeholders, with one commenter recommending 1 to 2 years to implement the new standards. CMS agreed, extending compliance dates to 2027.

Other commenters provided specific comments on the IGs used, including multiple commentors recommending use of TEFCQ QHINs over HL7 FHIR IGs, given the lack of maturity in the FHIR IGs. CMS responded and maintained their use of HL7 FHIR IGs. Other commenters recommended CMS provide technical assistance to those implementing the payer-to-payer API. CMS noted that it intends to host future Connectathons, as well as provide educational webinars and other public resources.

- Payer-to-Payer API Data Content Requirements

Many commenters expressed that using the same January 1, 2016, start date for the set of data that must be exchanged via the Payer-to-Payer API would include significant historical data that are unlikely to be relevant to a patient's current health status and ongoing care, and instead impose significant burden on payers. Those commenters urged CMS to establish a rolling period of time to the date of the exchange for the data content that must be shared. CMS agreed, finalizing its modification to limit payer to payer data exchange to only the previous 5 years.

Multiple commenters supported the exclusion of provider remittances and patient cost-sharing.

Multiple commenters recommended some types of prior authorization data be excluded from the Payer-to-Payer API. Specifically, CMS should exclude information about previously denied prior authorization, which could be used to limit care for patients, even they meet the new payer's criteria for the same service. CMS agreed, and modified its proposal accordingly, excluding prior authorization denials.

Several commenters recommended not including the quantity of services used to date due to the concern that health plan claims data updates are often delayed and, therefore, may not be a reliable source to track the number of authorized services used to date. CMS agreed and modified its information requirements accordingly.

- Identifying Previous and Concurrent Payers and Opt In

Multiple commenters expressed concern regarding processes for opting in and collecting previous/concurrent payer data occurring at the start of coverage, noting logistical challenges to collecting data at the time of a patient's enrollment, including document format and regulatory challenges to updating existing enrollment forms. Multiple commenters provided recommendations regarding actions for payers to take at the time of enrollment to facilitate collecting this information, such as defining specific data and updating enrollment forms. In addition, multiple commenters stated that payers should be permitted to collect a patient's opt in after enrollment. CMS agreed and finalized a modification to its proposal by extending the deadline for both requesting identifying information about

a patient's previous/concurrent payer(s) and seeking opt in from the patient to 1 week after the start of coverage, with certain differences among payers.

Many commenters expressed support for patients needing to opt into the Payer-to-Payer API, noting that it would provide patients with greater access and control over their information, as well as more privacy. Others expressed concern that it would result in lower rates of patient participation in the data exchange. CMS maintained that they believe patients are the owners of their data and therefore should have control over who has access to their data.

- Requesting Data Exchange from a Patient's Previous/Concurrent Payer(s) and Responding to such a Request

Many commenters supported our proposal to require impacted payers to request data from a patient's previous payer no later than 1 week after the start of coverage or obtaining previous/concurrent payer information and opt in permission from the patient. Other commenters suggested a variety of alternative timeframes for payers to request patient data from previous/concurrent payers. CMS maintained that 1 week is the appropriate period to require payers to make a request for patient data; the longer the period the less relevant those data could be, especially for patients with life-threatening conditions. However, CMS also determined that the proposed data request deadline was no longer feasible with the modified deadline for requesting previous/concurrent payer information and the patient's opt in to be no later than 1 week after the start of coverage. Therefore, they finalized a modification to their proposal, as noted above.

- Ongoing Data Exchange Requirements for Concurrent Coverage

One commenter recommended that CMS only require concurrent payers making quarterly data transmissions to send data that have been updated since the last data exchange. The commenter stated that this would reduce burden by allowing them to exchange a smaller set of data that can more easily be integrated into their patient records. CMS agreed that this was a reasonable solution to reduce burden, and modified its proposals accordingly.

A significant majority of commenters supported the proposal to require quarterly data exchange between concurrent payers because it would facilitate care

coordination. Some commenters suggested that a more frequent data exchange could benefit patients. Some commenters noted that even quarterly data exchange may miss key clinical events that would be useful for care coordination and recommended that the data exchange should take place monthly. On the other hand, a few commenters stated that impacted payers should only request additional data from concurrent payers when initiated by a member. CMS agreed with the majority of commenters that a quarterly cadence appropriately balances the benefits and burdens on payers.

- Data Incorporation and Maintenance

Multiple commenters supported the proposal to require payers to incorporate data they receive from other payers via the Payer-to-Payer API into their own patient records in order to ensure that a patient's record is not lost. Other commenters stated that they do not believe that payers are the appropriate holders of a patient's full medical record and that providers or patients themselves should be the maintainers of those data. CMS agreed that while in some cases a payer is not the best entity to hold a patient's longitudinal record, there is other technology available for patients to download their data, such as through the Patient Access API, and store it independently. They also referenced their modification to limit data within 5 years of the request.

Multiple commenters supported CMS' decision not to propose or establish a data retention requirement for patient records that would be different or longer than that required by current laws, regulations, and policies. Other commenters recommended that CMS set a minimum data retention timeframe. CMS maintained that they do not believe that additional data retention requirements are necessary at this time, given conflicts with potential rules.

- Patient Education Resources

Multiple commenters expressed support for CMS's proposed requirements related to resources to educate patients about the benefits of data exchange between payers, the patient's right to opt in and to withdraw their permission, and instructions for doing so. Multiple commenters supported CMS's proposals to require that patient educational resources be in nontechnical, simple, and easy to understand language.



CMS appreciated the feedback, and chose to modify its information requirement to be in “plan language” to be more straightforward and encourage payers to follow the Federal Government’s plain language guidelines.

Other commenters recommended that CMS develop resources, such as standardized language, tools, and delivery models, that payers could customize to ensure a consistent message to patients on what will be a confusing and complicated topic. CMS noted that they intend to provide templates or outlines for educational resources after this final rule is published and in time for payers to review and use prior to the compliance dates.

### **III. Payer to Payer Data Exchange in Medicaid and CHIP**

#### **Finalized Changes**

- Inclusion of Medicaid and CHIP FFS

CMS finalized to make the proposed payer to payer data exchange policies in this final rule applicable to state Medicaid and CHIP FFS programs.

- Medicaid and CHIP – Seeking Permission Using an Opt In Approach in the Payer-to-Payer API

CMS finalized that if a Medicaid or CHIP agency is exchanging information per CMS’ Payer to payer API programs with a managed care entity that they contract with, the requirement to obtain patient opt in would not apply.

CMS finalized for Medicaid and CHIP agencies implement a process to enable enrolled beneficiaries to opt in to payer to payer data exchange prior to the Payer to payer API compliance data. This would specifically require that the state Medicaid and CHIP agencies, rather than the managed care plan, be responsible for obtaining permission to share the patient’s data. The requirement to identify patients’ previous and/or concurrent payers would also apply to the state Medicaid and CHIP agencies instead of the managed care entities.

#### **Background/Rationale**

- Inclusion of Medicaid and CHIP FFS

Commenters supported applying the proposed requirements to Medicaid and CHIP FFS and agreed that such a policy would benefit Medicaid and CHIP beneficiaries who are covered by FFS by improving care coordination and continuity of care. Other commenters stated that the Payer-to-Payer API would reduce burden on patients and providers and allow state Medicaid agencies to operate more efficiently.

- Medicaid and CHIP – Seeking Permission Using an Opt In Approach in the Payer-to-Payer API

Multiple commenters recommended that CMS reexamine whether its interpretation of 42 CFR 431.306(d) and 457.1110(b) would prohibit Medicaid agencies from participating in HIEs. CMS disagreed with this interpretation.

Multiple commenters agreed with the proposal for state Medicaid and CHIP agencies to collect and manage patient decisions to opt into the payer-to-payer data exchange when beneficiaries are enrolled in Medicaid or CHIP managed care.

Multiple commenters agreed that collecting a beneficiary's choice to opt into the payer-to-payer data exchanges as part of existing Medicaid and CHIP eligibility and enrollment processes would be the most effective and technically feasible approach for most states operating managed care programs in Medicaid and CHIP and would streamline the process for beneficiaries. CMS agreed that the state Medicaid or CHIP program is the appropriate custodian of the patient's permission record, rather than the particular managed care plan or managed care entity through which a patient receives Medicaid or CHIP covered services.

Multiple commenters expressed concerns about state Medicaid and CHIP agencies' resources to collect and manage patient decisions to opt into the exchange of their data via the Payer-to-Payer API. CMS understood these concerns and noted their decision to extend compliance dates from 2026 to 2027.

## **E. Extensions, Exemptions and Exceptions (section II.C.5)**

### **I. Extensions and Exemptions for Medicaid and CHIP FFS Programs**

#### **Finalized Changes**

#### **Support for Proposed Medicaid and CHIP FFS Extension Policy:**





CMS acknowledged states for their ongoing efforts to return to normal Medicaid and CHIP operations post the COVID-19 Public Health Emergency (PHE) and the continuous enrollment condition. CMS noted that the final rule mandates impacted payers to implement and maintain Provider Access, Payer-to-Payer, and Prior Authorization APIs, emphasizing that impacted payers should have already implemented or initiated implementation of Patient Access and Provider Directory APIs, except for those with approved exceptions. No new Patient Access API is proposed, but additional data requirements and reporting metrics are outlined, with no new extensions, exemptions, or exceptions for the Patient Access API in the final rule.

#### **Concerns on Proposed State Medicaid and CHIP FFS Extension Policies:**

CMS thanked commenters for affirming the importance of holding payers accountable for implementing the APIs and recognizing that provider adoption, particularly of the Prior Authorization API, is crucial for achieving burden reduction. CMS acknowledged the significance of both payers and providers participating in the API provisions of the final rule to ensure widespread adoption. In alignment with the belief that provider participation is vital for the Prior Authorization API, CMS is finalizing a modification to the proposal, introducing new Electronic Prior Authorization measures to incentivize providers, including MIPS eligible clinicians, eligible hospitals, and CAHs, to use the Prior Authorization API under MIPS and the Medicare Promoting Interoperability Program.

CMS emphasized that while extensions and exemptions apply to the new API provisions, other policies must adhere to compliance dates established in the final rule. These include prior authorization information in the Patient Access API, details required under the finalized prior authorization process (such as specific denial reasons), and revised timeframes for issuing prior authorization decisions. CMS encouraged states to communicate their implementation plans for final rule policies, including those eligible for extension or exemption, to network and enrolled providers. Such communication is seen as crucial for helping providers prepare for procedural changes or inform vendors to make necessary system adjustments on a coordinated schedule.

#### **Equity Concerns and Exemptions:**



CMS agreed that addressing access and equity issues and avoiding a two-tiered system with potential barriers to care is crucial. CMS will grant a state an exemption from the Provider Access, Payer-to-Payer, and Prior Authorization APIs only if the state establishes an alternative plan to facilitate the electronic exchange and accessibility of the required information typically shared through the API. Specifically, CMS will consider granting a state an exemption from the Provider Access API requirement if the state has an alternative plan ensuring enrolled providers have efficient electronic access to the same required data through other means during the approved exemption period. States are expected to use efficient electronic prior authorization methods that reduce provider burden and enhance access to information about prior authorization requirements.

CMS emphasized that, considering the accessibility requirements, states implementing alternative plans must provide information in plain language to all patients and providers. Additionally, states are required to offer auxiliary aids and services to ensure effective communication with individuals with disabilities.

**Inclusion of Managed Care Plans in Flexibilities:**

CMS acknowledges and thanks commenters recommending an extension or exemption option for Medicaid managed care plans and CHIP managed care entities, aligning with CMS's approach to apply most policies uniformly across state Medicaid and CHIP FFS programs, as well as Medicaid managed care plans and CHIP managed care entities. However, CMS reiterates that the extension policy for state Medicaid and CHIP FFS programs aim to provide states making a good faith effort with additional time to navigate complex state procurement processes and secure necessary funding, personnel, and technical resources for successful implementation. The exemption policy for state Medicaid and CHIP FFS programs accommodate different enrollment models and considers states with relatively small FFS populations.

In response to comments requesting additional time for payers to implement Provider Access, Payer-to-Payer, and Prior Authorization APIs, CMS is extending compliance dates for policies requiring API development or enhancement to 2027. This grants all impacted payers an extra year compared to the initial proposal to implement requirements by 2026. CMS thanks commenters for their input.

CMS is finalizing the state Medicaid and CHIP FFS extension and exemption policies as proposed, without extending this option to other payers in the Medicaid program, such as Medicaid managed care plans. CMS does not agree with commenters suggesting each state be allowed to decide separately on extensions for managed care plans, emphasizing the final rule's purpose to encourage prompt adoption of these policies. CMS notes that Medicaid managed care plans, often operated by larger private organizations subject to the final rule, likely have the resources to efficiently implement these policies and leverage their work across Medicaid, MA, and Marketplace lines of business. CMS aims to avoid a system where fewer Medicaid beneficiaries have access to the benefits of the policies compared to those with other types of coverage.

#### **Additional Payers and Plan Types for Flexibilities:**

CMS thanked all commenters for their valuable input on extensions, exemptions, and exceptions for all payers. The extensions and exemptions policies are being finalized as proposed for state Medicaid and CHIP FFS programs, without extension to additional payers. CMS acknowledged that state Medicaid and CHIP FFS programs encounter unique challenges distinct from other impacted payers. Unlike other payers, these programs lack multiple discrete health care plans, making it challenging to balance implementation costs across different enrollment scales. CMS recognizes that many states face complex procurement and staffing challenges not applicable to non-governmental organizations.

CMS acknowledged that Health Information Exchanges (HIEs) can be valuable partners for payers during API implementation. The rule does not prohibit states from collaborating with HIEs to meet their requirements. Additional discussions regarding HIEs can be found in sections II.B.3.b.iii. and II.C.3.a. of this final rule.

#### **Exemptions for States Implementing Electronic Prior Authorization Solutions:**

CMS did not propose extensions or exemptions for MA organizations or Medicaid managed care plans, including those integrating managed care Medicare and Medicaid benefits (such as D-SNPs or applicable integrated plans). CMS acknowledged and thanked commenters for their input, providing explanations for excluding Medicaid managed care plans in previous responses.



CMS believes that most MA organizations are supported by entities with operational and technical infrastructures capable of meeting API requirements, leveraging existing staff and vendor resources from the implementation of Patient Access and Provider Directory APIs. The operational infrastructure of MA organizations should enable them to analyze and implement the requirements for new APIs based on their expertise. CMS emphasized that, since extensions or exemptions for MA organizations were not proposed in the initial rule, such a policy cannot be finalized for these entities in this rule.

### **Exemptions for Electronic Prior Authorization Implementation**

CMS noted exemption option is available for states with small FFS populations, providing relief and allowing them to establish alternative plans for enrolled providers to have efficient electronic access to the required information through other means during the exemption period. However, exemptions will not be granted in situations where state law conflicts with the final rule, as the final rule pre-empts any conflicting state law.

### **Request for Two 1-Year Extensions:**

After considering the comments received and for the reasons outlined in their response, CMS is extending the compliance dates for all policies requiring API development or enhancement, as finalized in this rule, to begin on January 1, 2027. This extension provides additional time for the refinement and advancement of the FHIR standard and Implementation Guides (IGs) to support all policies in this final rule. Specifically, this extension applies to the compliance dates for the Provider Access, Payer-to-Payer, and Prior Authorization APIs.

State Medicaid and CHIP FFS programs are eligible to apply for up to a 1-year extension, consistent with the proposal. CMS acknowledged the importance of providing states with this flexibility to address challenges and ensure a smoother implementation process.

### **Support for Exemptions for State Medicaid and CHIP FFS Programs:**

CMS thanked commenters for their support of the proposed exemption process, acknowledging the simultaneous encouragement for payers to secure the necessary resources for implementing technology related to prior authorization and



other APIs finalized in this rule. CMS confirmed that the policy in this final rule does not apply to Federal Emergency Services Programs (FESPs) and clarified that other payers are not currently considered eligible for exemptions, extensions, or exceptions.

**Concerns about Incentivizing Managed Care Enrollment:**

CMS acknowledged the need to balance benefits to small populations of beneficiaries with the operational burden and costs imposed on states. CMS emphasized that exemptions will not be approved unless a state establishes an alternative plan ensuring enrolled providers have efficient electronic access to the same information, including prior authorization details, through other means during the exemption period. Alternatively, states must provide efficient electronic access to other payers. CMS thanked commenters for their input.

Additionally, state agencies with approved exemptions must adhere to policies not requiring API development or enhancement for their FFS populations, such as reduced prior authorization decision timeframes, providing specific denial reasons, and reporting prior authorization metrics. These policies, aimed at mitigating barriers to care and improving transparency of information between states and providers, align with the overall scope of this final rule to address challenges with prior authorization.

Regarding the methodology for states to apply and be approved for an exemption, CMS believes it has provided a threshold where a state can appropriately claim an exemption without influencing the enrollment process or individual enrollee's decisions inappropriately. CMS emphasized the use of enrollment brokers for choice counseling and enrollment processing to protect enrollees from undue pressure during the enrollment process. States were reminded of enrollee protections specified at 42 CFR 438.54 and 457.1210 for Medicaid and CHIP managed care enrollment, as well as disenrollment rights specified at 42 CFR 438.56(c) and 457.1212, respectively.

**Exemptions for States with Managed Care Populations:**

CMS thanked the commenter for bringing attention to the fact that some states may have larger populations in Fee-for-Service (FFS) where beneficiaries receive limited comprehensive benefits, potentially having limited value from the APIs. CMS



acknowledged that the condition for exemption approval aims to prevent any FFS population from experiencing diminished healthcare delivery or information exchange capabilities due to an approved exemption. The intent of the exemption is to alleviate the cost burden of implementing API provisions on state Medicaid and/or CHIP agencies with small FFS populations, irrespective of the scope of their benefit package. CMS emphasized that an exemption will be granted if the state, to CMS's satisfaction, establishes meeting the criteria for the exemption and has developed an alternative plan ensuring that enrolled providers have efficient electronic access to the same information through other means during the exemption period, including patient information and prior authorization details.

### **Background/Rationale**

In the proposed rule, the challenges faced by state Medicaid and CHIP Fee-For-Service (FFS) agencies were highlighted, particularly in terms of financing and operational constraints unique to these agencies. Issues such as the need for legislative approval for public procurement processes and the time-consuming nature of onboarding contractors for API development were discussed. The proposed rule addressed these concerns by suggesting a process for states to seek extensions or exemptions from implementing and maintaining Provider Access, Payer-to-Payer, and Prior Authorization APIs. States could request a one-time, 1-year extension through their annual Advance Planning Document (APD) for Medicaid Management Information System (MMIS) operations expenditures. An exemption could be sought if at least 90 percent of Medicaid or CHIP beneficiaries were enrolled in managed care organizations (MCOs). The responsibility for obtaining beneficiaries' permission and payer data exchange in payer-to-payer scenarios was assigned to state Medicaid and CHIP programs, not managed care plans. Exemptions were specified to apply only to API requirements, not payer-to-payer data exchange, to ensure compliance with obligations of managed care plans. While no extension process was proposed for Medicaid managed care plans and CHIP managed care entities, it was emphasized that these entities, often part of larger organizations, were actively working to develop IT infrastructure for compliance. The implementation times finalized in the rule were deemed applicable to support policy goals, particularly given that the majority of Medicaid beneficiaries receive benefits through managed

care delivery systems. Reference to the relevant sections of the proposed rule was provided for additional context.

### **Support for Proposed Medicaid and CHIP FFS Extension Policy:**

Commenters expressed support for the proposed Medicaid and CHIP FFS extension policy, urging CMS to finalize flexibility in compliance with Provider Access, Payer-to-Payer, and Prior Authorization APIs. Several highlighted challenges faced by state Medicaid and CHIP agencies, particularly related to the conclusion of the COVID-19 public health emergency, impacting IT and personnel resources. Suggestions were made regarding the inclusion of specific APIs in extensions, exemptions, and exceptions, with some recommending extending flexibilities to all APIs in the rule. Clarity was also requested from CMS regarding exemption and extension provisions for Patient Access API requirements.

### **Concerns on Proposed State Medicaid and CHIP FFS Extension Policies:**

Multiple commenters expressed concerns about the proposed state Medicaid and CHIP FFS extension policies, emphasizing the impact on Medicaid enrollees and the crucial role of provider adoption for the proposed rule's burden reduction goals. Some commenters urged CMS not to grant certain payers extensions, as it could hinder provider adoption of essential technology. While one commenter appreciated CMS for proposing extensions, they emphasized the pivotal role of provider adoption in achieving burden reduction. The commenter highlighted the importance of a percentage of prior authorizations being electronic for a return on investment, emphasizing the need for payers to adhere to the rule's requirements to incentivize provider investment in necessary technology.

### **Equity Concerns and Exemptions:**

A commenter expressed concern about the exemption for APIs, stating that it creates an unfair two-tiered system that may disadvantage people with disabilities. The commenter highlighted the existing high barriers to care for this group due to administrative burdens and uncertainties related to prior authorization. The proposed exemption process, according to the commenter, could leave certain FFS Medicaid populations, including a significant number of people with disabilities, without access to the benefits of streamlining the prior authorization process

through Patient Access, Provider Access, and Payer-to-Payer APIs. The commenter acknowledged potential challenges in developing infrastructure for a relatively small FFS population but pointed out that individuals receiving Home and Community-Based Services (HCBS) through waivers carved out of managed care might be excluded from the proposed API exemption, missing out on the streamlined prior authorization process. Another commenter sought clarification on how CMS considered health equity in proposing exemptions for some state Medicaid and CHIP programs. Other commenters disagreed with the proposed exemptions, urging their withdrawal to make APIs available to all Medicaid beneficiaries. Additionally, one commenter raised concerns that states near the proposed exemption threshold might be incentivized to pressure beneficiaries into managed care to qualify for the exemption.

#### **Inclusion of Managed Care Plans in Flexibilities:**

Multiple commenters recommended that CMS extend proposed flexibilities, including both extensions and exemptions, to include managed care plans. Some commenters suggested that each state should have the authority to decide whether to grant extensions to managed care plans. It was observed that managed care plans typically have more resources than state Medicaid and CHIP FFS programs, making them better positioned to meet the rule requirements within the specified timeframe. Conversely, another commenter proposed that state Medicaid agencies provide a 1-year extension specifically to managed care plans.

#### **Additional Payers and Plan Types for Flexibilities:**

Multiple commenters offered recommendations on expanding eligibility for extensions, exemptions, and exceptions, advocating for CMS to extend flexibilities to all impacted payers. One suggestion proposed allowing state Medicaid and CHIP agencies with a direct relationship with patients and providers to be eligible for these flexibilities. Another commenter recommended creating an exception process for state Medicaid agencies in regions with Health Information Exchanges (HIEs) that offer equivalent data access as the Provider Access API, aiming to avoid resource duplication and confusion among providers. Similarly, there were calls for creating exception processes for Medicaid agencies in states with robust HIEs. Additionally, commenters urged CMS to consider exception and extension criteria for plans facing





operational challenges due to proposed timelines and requirements that could jeopardize their ability to function effectively.

### **Exemptions for States Implementing Electronic Prior Authorization Solutions:**

Some commenters recommended that CMS include extensions and/or exemptions in the proposal for MA organizations, Special Needs Plans (SNPs), Dual-Eligible Special Needs Plans (D-SNPs), or Institutional Special Needs Plans (I-SNPs). Specifically, one commenter suggested permitting extensions and exemptions for MA organizations offering integrated D-SNPs, particularly if CMS does not finalize a phased-in approach to implementation. The commenter emphasized that these payers are grappling with the challenge of undoing current flexibilities implemented due to the Public Health Emergency (PHE) while also facing significant requirements in the coming years as outlined in the CY 2024 MA and Part D final rule (88 FR 22120). Additionally, another commenter requested that CMS consider whether there may be appropriate circumstances allowing very small MA organizations, such as SNPs or I-SNPs, to seek a one-time extension to the compliance dates.

### **Exemptions for Electronic Prior Authorization Implementation**

Some commenters suggested that CMS should provide exemptions for states that are already in the process of implementing electronic prior authorization solutions or have state-level policies that conflict with the proposed Prior Authorization API requirements.

### **Request for Two 1-Year Extensions:**

Multiple commenters recommended that CMS consider allowing states to obtain two 1-year extensions. One commenter emphasized that an additional 1-year extension would enhance states' ability to meet the proposed requirements. Another commenter highlighted that states face certain challenges beyond their control that may prolong the implementation process.

### **Support for Exemptions for State Medicaid and CHIP FFS Programs:**

Multiple commenters expressed support for CMS's proposal regarding exemptions for state Medicaid and CHIP FFS programs, recommending the finalization of these proposed flexibilities for implementing Provider Access, Payer-to-Payer, and Prior

Authorization APIs. One commenter, in reviewing exemption requests and compliance dates in the proposed rule, highlighted the urgency of implementing a comprehensive systems integration platform for the Medicaid Eligibility Systems (MES). This urgency is particularly due to the end of support for another legacy system. Another commenter recommended a flexible interpretation for the exemption process, emphasizing that it would not be reasonable to require states to build APIs for a Federal Emergency Services Program (FESP). The commenter explained that some agencies report having a high number of FFS enrollees in an FESP, making it challenging for them to meet the requirement, as less than 90 percent of their members are technically enrolled in managed care.

#### **Concerns about Incentivizing Managed Care Enrollment:**

A commenter raised concerns that states with managed care populations close to the proposed exemption threshold might be incentivized to pressure beneficiaries into managed care to qualify for the exemption. Another commenter pointed out that larger states qualifying for an exemption would have a total number of FFS beneficiaries greater than the total Medicaid population of smaller states that would not qualify for the exemption.

#### **Exemptions for States with Managed Care Populations:**

A commenter urged CMS to adopt a flexible interpretation for the exemption process, specifically for the API requirements applicable to Medicaid agencies with at least 90 percent of their members enrolled in managed care. The commenter highlighted that some states have a significant number of FFS beneficiaries in a Federal Emergency Services Program (FESP) that only covers emergency care. The commenter argued that requiring a state to build APIs for beneficiaries and programs with such a narrow scope of services would be unreasonable.

#### **II. Exception for QHP Issuers**

##### **Finalized Changes**

##### **Support for QHP Issuer Exceptions:**

CMS acknowledged and appreciated the support for the policy allowing Qualified Health Plans (QHPs) an exception for API development or enhancement. This exception is granted when the Federally Facilitated Exchange (FFE) determines that



making QHPs available is in the interests of qualified individuals in the relevant states. The policy aligns with the exception finalized for the Patient Access API, ensuring consistency. CMS emphasized that allowing QHP issuers to offer plans through the FFE is generally in the best interest of patients, aiming to prevent patients from going without access to QHP coverage due to an issuer's inability to implement APIs.

### **Concerns and Recommendations on QHP Issuer Exceptions:**

CMS acknowledged concerns raised by commenters about delayed implementation but, considering the support for the proposed exceptions process, CMS is finalizing this exception as proposed. The decision aims to ensure a variety of coverage options for Federally Facilitated Exchange (FFE) enrollees. Acknowledging that issuers participating in FFEs vary in terms of available resources and readiness to adopt new requirements, CMS will continue granting exceptions to Qualified Health Plan (QHP) issuers on the FFEs based on rules at 45 CFR 156.221(h), 156.222(c), and 156.223(d).

CMS appreciated the feedback and experience gained in implementing the existing exception for the Patient Access API. The agency emphasized the importance of balancing access to information with robust QHP issuer participation on the FFEs. The final policies intend for all impacted payers to provide patients with the benefits of the APIs as soon as they are financially and operationally able. CMS highlighted the requirement for payers seeking exemptions to offer alternative options to support the policies' intent and encouraged payers to explore API implementation options for long-term efficiency.

### **Background/Rationale**

For Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges (FFE), an exception process was proposed for the Provider Access, Payer-to-Payer, and Prior Authorization APIs in cases where issuers applying for QHP certification cannot meet the proposed requirements. The process involves including a narrative justification as part of the QHP application, outlining reasons for the inability to meet requirements, the impact of non-compliance on providers and enrollees, current or proposed means of providing required information, and solutions with a compliance timeline.

In this final rule, it is reiterated that QHP issuers on the FFEs submit a new application annually, and the exception information is part of the QHP Certification application submission. Changes in the size, financial condition, or capabilities of the QHP issuer that may enable API implementation can be reflected in the annual application. The rule received a few comments on the proposed exceptions for QHPs.

### **Support for QHP Issuer Exceptions:**

Multiple commenters expressed support for the proposed exception process for QHP issuers on the Federally Facilitated Exchanges (FFE). They emphasized the necessity of this policy and recommended CMS to finalize the proposal allowing exceptions for QHP issuers on the FFEs concerning compliance with all proposed APIs.

### **Concerns and Recommendations on QHP Issuer Exceptions:**

Multiple commenters raised concerns about the proposed exception process for QHP issuers on the FFEs. These concerns included the ability for QHP issuers to be certified even with an exception, the suggested limitation of exceptions for the Provider Access API, and the need for CMS to clarify that QHP issuers must eventually comply with the proposed requirements. A commenter also expressed concerns about the financial position of QHP issuers and recommended conditioning exceptions on certain financial criteria.

## **F. Improving Prior Authorization Processes (section II.D)**

### **I. Electronic Options for Prior Authorization**

#### **Finalized Changes**

CMS finalized their proposal as written to require impacted payers to implement an HL7 FHIR API that would work in combination with the adopted HIPAA transaction standard to conduct the prior authorization process.

#### **Background/Rationale**

Many commenters supported CMS's efforts to implement a standardized API that makes payers' prior authorization and other documentation requirements electronically accessible to providers and that supports a more streamlined prior authorization request and response process. Multiple commenters believe this



change will offer many benefits for patients and providers, including increasing access to care for patients and increasing providers' understanding of prior authorization requirements by providing upfront information about which services require prior authorization and what type of documentation is required to support approval of a prior authorization request; and increasing automation in the submission, receipt, and processing of requests, which could support more timely responses.

CMS acknowledged concerns about the new technology and processes associated with the Prior Authorization API, including implementation challenges, potential conflicts with existing workflows, and increased workload for initially implementing the Prior Authorization API. It is in part based on these considerations that CMS decided to modify their proposed compliance dates so that the impacted payers and providers alike will have sufficient time to conduct testing on the newly structured prior authorization process.

## **II. Proposed Requirements for Payers: Implement an API for Prior Authorization Requirements, Documentation, and Decision**

### **Finalized Changes**

CMS amended their original proposal and extended compliance dates for impacted payers. CMS finalized that payers are required to implement the Prior Authorization API for all prior authorization rules and requirements for items and services, excluding drugs, by January 1, 2027 (for Medicaid managed care plans and CHIP managed care entities, by 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 finalized their proposal requiring impacted payers to implement and maintain a Prior Authorization API that is populated with its list of covered items and services, can identify documentation requirements for prior authorization approval, and supports a prior authorization request and response. These Prior Authorization APIs must also communicate whether the payer approves the prior authorization request (and the date or circumstance under which the authorization ends), denies the prior authorization request (and a specific reason for the denial), or requests more information.

## **Background/Rationale**

Multiple commenters believe this change will offer many benefits for patients and providers, including increasing access to care for patients and increasing providers' understanding of prior authorization requirements by providing upfront information about which services require prior authorization and what type of documentation is required to support approval of a prior authorization request; and increasing automation in the submission, receipt, and processing of requests, which could support more timely responses.

CMS acknowledged concerns about the new technology and processes associated with the Prior Authorization API, including implementation challenges, potential conflicts with existing workflows, and increased workload for initially implementing the Prior Authorization API. It is in part based on these considerations that CMS decided to modify their proposed compliance dates so that the impacted payers and providers alike will have sufficient time to conduct testing on the newly structured prior authorization process.

### **III. Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorization**

#### **Finalized Changes**

CMS finalized that beginning in 2026, impacted payers must provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request. As with all policies in this final rule, this provision does not apply to prior authorization decisions for drugs.

#### **Background/Rationale**

CMS noted that this final policy is an effort to improve the communication about denials from an impacted payer in response to a request for a prior authorization through existing mechanisms, such as electronic portals, telephone calls, email, standard transactions, or other means. Multiple commenters expressed their support for CMS's proposal to require impacted payers to provide specific reasons for prior authorization denials, regardless of the mechanism used to submit the prior authorization request. Multiple commenters also specifically expressed support for



requiring impacted payers to provide the reasons for denial as part of the information included in the Prior Authorization and Patient Access APIs.

Multiple commenters recommended that CMS be more specific about which prior authorization decision information payers should include as well as how they should provide this information. Specifically, multiple commenters recommended that CMS further specify the level of detail that impacted payers must provide about their reasons for denial. CMS noted that when implemented, the Prior Authorization API could mitigate some denials by providing information about the documentation and information or data necessary to support a prior authorization request for the service or item.

#### **IV. Requirement for Prior Authorization Decision Timeframes and Communications**

##### **Finalized Changes**

CMS finalized their proposal requiring impacted payers (excluding QHP issuers on the FFEs) to send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests. Impacted payers are expected to start January 1, 2026.

##### **Background/Rationale**

Multiple commenters disagreed with the proposal to exclude QHP issuers on the FFEs from prior authorization shortened decision timeframe requirements and recommended that CMS reconsider the exclusion of these payers. CMS noted that they believe the current standard adequately protects patient interests. QHP issuers on the FFEs are required to provide notification of a plan's benefit determination within 15 days for standard authorization decisions and within 72 hours for expedited requests; thus, QHP issuers on the FFEs have the same timeframe for expedited authorization decisions as other impacted payers in this final rule.

#### **V. Requirement for Timing of Notifications Related to Prior Authorization Decisions**

##### **Finalized Changes**



CMS finalized their proposals requiring timing of notifications related to prior authorization decisions for the following payers below:

**TABLE E1: PRIOR AUTHORIZATION DECISION TIMEFRAMES FOR IMPACTED PAYERS BEGINNING IN 2026 (EXCLUDING DRUGS)**

Payer	Final Expedited Prior Authorization Decision Timeframes	Final Standard Prior Authorization Decision Timeframes
MA Organizations and Applicable Integrated Plans	As expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.* 42 CFR 422.572(a) 42 CFR 422.631(d)(2)(iv)	As expeditiously as the enrollee's health condition requires but no later than 7 calendar days after receiving the request for the standard organization determination* and standard integrated organization decision. 42 CFR 422.568(b)(1) 42 CFR 422.631(d)(2)(i)(B)
Medicaid Managed Care Plans	As expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service. 42 CFR 438.210(d)(2)	As expeditiously as the enrollee's condition requires and within State established timeframes that may not exceed 7 calendar days after receiving the request for service. 42 CFR 438.210(d)(1)
CHIP Managed Care Entities	As expeditiously as the enrollee's health condition requires but no later than 72 hours after receipt of the request for service, unless a shorter minimum time frame is established under state law. 42 CFR 457.1230(d)	As expeditiously as the enrollee's condition requires but no later than 7 calendar days after receiving the request for service, unless a shorter minimum time frame is established under state law. 42 CFR 457.1230(d)
Medicaid FFS	As expeditiously as a beneficiary's health condition requires, but in no case later than 72 hours after receiving the request, unless a shorter minimum time frame is established under state law. 42 CFR 440.230(e)(1)(ii)	As expeditiously as a beneficiary's health condition requires, but in no case later than 7 calendar days after receiving the request, unless a shorter minimum timeframe is established under state law. 42 CFR 440.230(e)(1)(i)
CHIP FFS	In accordance with the medical needs of the patient, but no later than 72 hours after receiving the request for an expedited determination. 42 CFR 457.495(d)(1)	In accordance with the medical needs of the patient, but no later than 7 calendar days after receiving the request for a standard determination. 42 CFR 457.495(d)(1)
QHP Issuers on the FFEs	As soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim. 45 CFR 147.136(b)(3)(i)	A reasonable period of time appropriate to the medical circumstances but not later than 15 days after receipt of the claim. 45 CFR 147.136(b)(3)(i)

\*Applicable integrated plans may have shorter timeframes as required by a state (42 CFR 422.629(c) allows states to implement shorter timeframes).

## Background/Rationale

Commentators expressed their concerns around the timeframes, noting that they should be shorter. CMS stated that though they anticipate the prior authorization API will introduce additional efficiencies into the prior authorization process, they are



uncertain that a truncated decision timeframe would be possible until they have completed further data collection analysis after the implementation of the API.

CMS noted that if a payer fails to meet the timeline for approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete the processing of the authorization or if there are other reasons for the delay in a decision. The 72-hour requirement for expedited requests is measured in hours, whereas the 7-day requirement for standard requests is measured in calendar days. In the case of expedited and standard requests, the timeframes are 72 hours and 7 days, respectively, unless a shorter minimum timeframe is established under state law.

## **VI. Public Reporting of Prior Authorization Metrics**

### **Finalized Changes**

CMS is requiring impacted payers to publicly report certain prior authorization aggregated metrics annually by posting them on their website. CMS finalized their requirement for impacted payers to make reports available annually on all of the following:

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



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

These operational or process-related prior authorization policies are being finalized with a compliance date starting January 1, 2026, and the initial set of metrics must be reported by March 31, 2026.

### **Background/Rationale**

CMS noted that they intend to support transparency and accountability and enable patients to access data that are meaningful and easy to use for decision-making and understanding the prior authorization processes. CMS stated that the metrics they are finalizing represent the most significant issues for both patients and providers identified over the past decade on a national level, including the CMS listening sessions. Furthermore, CMS noted that payers can supplement the information they report with additional metrics on prior authorization. CMS may consider additional reporting options in the future.

## **G. Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program (section II.E)**

### **I. Electronic Prior Authorization**

#### **Finalized Changes**

CMS finalized, with modifications, that starting with the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians will report the Electronic Prior Authorization measure, and starting with the CY 2027 EHR reporting period, eligible hospitals and CAHs will report the Electronic Prior Authorization measure.



CMS finalized, with modifications, the Electronic Prior Authorization measure and structured it as an attestation (yes/no) measure for both MIPS eligible clinicians and eligible hospitals and CAHs. The MIPS eligible clinician, eligible hospital, or CAH will submit an attestation about whether or not they submitted the Prior Authorization API to submit at least one prior authorization request electronically using data from CEHRT for one medical item or service (excluding drugs) or claim an applicable exclusion to report the modified Electronic Prior Authorization measures.

CMS finalized that a MIPS eligible clinician, eligible hospital, or CAH would fail the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category if they did not report the measure as specified, did not meet the minimum reporting requirements, and were not considered a meaningful EHR user. CMS finalized that measures will not be scored with points for completion or failure. A “yes” response on the attestation, or an applicable exclusion claim, would satisfy the measures. A failure would be a “no” response on the attestation and the MIPS eligible clinician, eligible hospital or CAH would not be considered a meaningful EHR user. After a failure in the Promoting Interoperability performance category, a MIPS eligible clinician would receive a score of zero, equaling 25 percent of their MIPS total score. After a failure in the Medicare Promoting Interoperability Program (unless the eligible hospital or CAH receives a hardship exception), an eligible hospital or CAH would face a downward payment adjustment.

### **Background/Rationale**

Many commenters supported the proposed Electronic Prior Authorization measure under the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program. CMS received positive feedback that the Electronic Prior Authorization measure will incentivize MIPS eligible clinicians, eligible hospitals, and CAHs to use the Prior Authorization API to automate the prior authorization process, potentially resulting in faster care delivery. CMS noted that providers not in the MIPS or the Medicare Promoting Interoperability Program could still leverage the Prior Authorization APIs to improve efficiency and reduce administrative burdens. CMS stated that the finalized policies aim to streamline the existing prior authorization process so providers can focus on improving patient outcomes instead of administrative burdens.

CMS received comments expressing the view that additional time for implementation would be beneficial. CMS agreed, and modified the timeframe provisions from the proposed policy that began with the CY 2026 performance period/2028 MIPS payment year and the CY 2026 EHR reporting period to increase adjustment time to the new electronic prior authorization workflow using the Prior Authorization API. CMS finalized a modification to its proposal to begin with the CY 2027 performance period/2029 MIPS payment year for MIPS and the CY 2027 EHR reporting period for the Medicare Promoting Interoperability Program.

CMS received feedback from commenters that shared concerns about the burdens of calculating a numerator and denominator as proposed for the Electronic Prior Authorization measure. CMS agreed and modified the Electronic Prior Authorization measure to be an attestation-based yes/no measure, rather than a numerator and denominator measure that required data collection, to reduce any burden on MIPS eligible clinicians, eligible hospitals, and CAHs. The yes/no measure would be used by providers to indicate whether they used a Prior Authorization API to submit at least one electronic prior authorization during the applicable performance period/MIPS payment year or EHR reporting period.

CMS noted it will work with ONC on future updates to the ONC Health IT Certification Program around electronic prior authorization to improve health care providers' capabilities to interact with the Prior Authorization APIs.

## **H. Interoperability Standards for APIs**

### **I. Modifications to Required Standards for APIs**

#### **Finalized Changes**

CMS finalized several changes regarding interoperability standards for application programming interfaces (APIs).

- Patient Access API

CMS finalized the required standards as proposed, with modifications to incorporate expiration dates adopted by the Office of the National Coordinator for Health Information Technology (ONC) at 45 CFR 170.215(b)(1)(i) and (c)(1).

- Provider Directory API

CMS finalized the proposal with modifications to incorporate the expiration date ONC adopted at 45 CFR 170.215(b)(1)(i), and to remove the SMART App Launch IG at 45 CFR 170.215(c)(1) and OpenID Connect Core at 45 CFR 170.215(e), which were erroneously included in the proposed rule.

- Provider Access to API

CMS finalized the proposal with modifications to not require OpenID Connect Core at 45 CFR 170.215(e) and with modifications to incorporate the expiration dates ONC adopted at 45 CFR 170.215(b)(1)(i) and (c)(1).

- Payer-to-Payer API

CMS has finalized its proposal with modifications to not require the SMART App Launch IG at 45 CFR 170.215(c) and OpenID Connect Core at 45 CFR 170.215(e), and to incorporate the expiration date ONC adopted at 45 CFR 170.215(b)(1)(i).

- Prior Authorization API

The proposal has been finalized with modifications to not require OpenID Connect Core at 45 CFR 170.215(e) and to incorporate expiration dates ONC adopted at 45 CFR 170.215(b)(1)(i) and (c)(1).

### **Background/Rationale**

Many commenters expressed concern with the FHIR standard, noting that the HL7 Da Vinci IGs that support the Patient Access API has not reached widespread adoption and maturity. Several commenters agreed that using FHIR-based standards to facilitate data transport across the industry and that FHIR-based exchange is technically feasible for both payers and providers to adopt and implement. CMS disagreed that FHIR is not mature, noting that the primary components of the FHIR standard are mature, as are the standards they required in the rule.

Various commenters shared concerns regarding the proposed technical standards and IG provisions outlined in the proposed rule. Commenters also noted that technical challenges around health information exchange could persist despite these proposals and that technical standards lack the specificity to properly support the interoperable exchange of data. CMS understood these concerns but believes that their approach optimally balances the need for them to provide directional guidance without locking implementers into the versions of the recommended IGs that were available at the time of the proposed rule.

## **II. Recommended Standards to Support APIs**

### **Finalized Changes**

- Previous Recommendations

CMS has withdrawn its December 2020 Interoperability proposed rule, which proposed to require certain impacted payers to use specific implementation guides (IGs). Additionally, CMS has recommended IGs that are relevant to each of the APIs, which may be used in addition to the required standards at 45 CFR 170.215.

- Recommending vs. Requiring Implementation Guides

CMS has determined that it will only recommend, not require the use of IGs. CMS has previously recommended certain IGs including, CARIN for Blue Button, PDex, PDex U.S. Drug Formulary, PDex Plan Net, CRD, DTR, and PAS. These IGs can be used for Patient Access, Provider Access, Provider Directory, Payer-to-Payer, and Prior Authorization APIs. While CMS did not require the use of IGs presently, it may require payers use IGs once they have reached maturity in future rulemaking. CMS acknowledged the potential for implementation variation which could limit interoperability and will monitor future IG development.

- Flexibility Provision

CMS has finalized a provision that allows payers the flexibility to use updated versions of certain standards required for the APIs in the final rule. This provision aims to accommodate changes and updates in IGs while ensuring compliance with API standards.

### **Background/Rationale**



Multiple commenters sent their support for CMS to recommend, rather than require, the use of IGs. Several commenters also noted the lack of outside involvement in the development phase for some IGs. On the other hand, multiple commenters urged CMS to require the use of IGs, adhering to its December 2020 proposal. Multiple commenters recommended CMS require impacted payers to use the CARIN for Blue Button, HL7® FHIR® Da Vinci Patient Coverage Decisions Exchange (PCDE), PDex, PDex U.S. Drug Formulary, PDex Plan Net, CRD, DTR, and PAS IGs while allowing for adaptability and advancement of those IGs over time. CMS received significant feedback on both sides regarding the requirement of IGs versus the recommendation of IGs, which suggested that there was not consensus on the issue. CMS acknowledges that by not requiring all available IGs, there is potential for implementation variation in these APIs that could limit interoperability and possibly lead to re-work for implementers if requirements are introduced later. CMS stated that it believes that recommending, but not requiring, the specific IGs will allow for flexibility within the industry to allow for additional improvements to be made without locking implementers into versions of IGs available at the time.

### III. Proposed Standards to Support APIs

#### Finalized Changes

**TABLE H1: USE OF INTEROPERABILITY STANDARDS FOR REQUIRED APIs**

Section	Requirement	Regulations for Each Impacted Payer					QHPs on the FFEs
		Medicare Advantage	Medicaid FFS	Medicaid Managed Care	CHIP FFS	CHIP Managed Care	
II.G.2.	Patient Access API (Effective date of the final rule)	42 CFR 422.119(c)(1)	42 CFR 431.60(c)(1)	Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5)	42 CFR 457.730(c)(1)	Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d)	45 CFR 156.221(c)(1)
II.G.2.	Provider Access API (Compliance date January 1, 2027)	42 CFR 422.121(a)(1)	42 CFR 431.61(a)(1)	Through cross reference to 42 CFR 431.61(a) at 42 CFR 438.242(b)(7)	42 CFR 457.731(a)(1)		45 CFR 156.222(a)(1)
II.G.2.	Provider Directory API (Effective date of the final rule)	Through cross reference to 42 CFR 422.119(c) at 42 CFR 422.120(a)	Through cross reference to 42 CFR 431.60(c) at 42 CFR 431.70(a)	Through cross reference to 42 CFR 431.70 at 42 CFR 438.242(b)(6)	Through cross reference to 42 CFR 457.730(c) at 42 CFR 457.760(a)		N/A
II.G.2.	Payer-to-Payer API (Compliance date January 1, 2027)	42 CFR 422.121(b)(1)	42 CFR 431.61(b)(1)	Through cross reference to 42 CFR 431.61(b)(1) at 42 CFR 438.242(b)(7)	42 CFR 457.731(b)(1)		45 CFR 156.222(b)(1)
II.G.2.	Prior Authorization API (Compliance date January 1, 2027)	42 CFR 422.122(b)	42 CFR 431.80(b)	Through cross reference to 42 CFR 431.80(b) at 42 CFR 438.242(b)(7)	42 CFR 457.732(b)		45 CFR 156.223(b)



**TABLE H2: USE OF UPDATED STANDARDS FOR THE REQUIRED APIs**

Section	Requirement	Regulations for Each Impacted Payer					QHPs on the FFEs
		Medicare Advantage	Medicaid FFS	Medicaid Managed Care	CHIP FFS	CHIP Managed Care	
II.G.2.	Patient Access API (Effective date of the final rule)	42 CFR 422.119(c)(4)	42 CFR 431.60(c)(4)	Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5)	42 CFR 457.730(c)(4)	Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d)	45 CFR 156.221(c)(4)
II.G.2.	Provider Access API (Compliance date January 1, 2027)	Through cross reference to 42 CFR 422.119(c)(4) at 42 CFR 422.121(a)(1)	Through cross reference to 42 CFR 431.60(c)(4) at 42 CFR 431.61(a)(1)	Through cross reference to 42 CFR 431.61(a) at 42 CFR 438.242(b)(7)	Through cross reference to 42 CFR 457.730(c)(4) at 42 CFR 457.731(a)(1)		Through cross reference to 45 CFR 156.221(c)(4) at 45 CFR 156.222(a)(1)
II.G.2.	Provider Directory API (Effective date of the final rule)	Through cross reference to 42 CFR 422.119(c)(4) at 42 CFR 422.120(a)	Through cross reference to 42 CFR 431.60(c)(4) at 42 CFR 431.70(a)	Through cross reference to 42 CFR 431.70 at 42 CFR 438.242(b)(6)	Through cross reference to 42 CFR 457.730(c)(4) at 42 CFR 457.760(a)	N/A	
II.G.2.	Payer-to-Payer API (Compliance date January 1, 2027)	Through cross reference to 42 CFR 422.119(c)(4) at 42 CFR 422.121(b)(1)	Through cross reference to 42 CFR 431.60(c)(4) at 42 CFR 431.61(b)(1)	Through cross reference to 42 CFR 431.61(b)(1) at 42 CFR 438.242(b)(7)	Through cross reference to 42 CFR 457.730(c)(4) at 42 CFR 457.731(b)(1)	Through cross reference to 45 CFR 156.221(c)(4) at 45 CFR 156.222(b)(1)	
II.G.2.	Prior Authorization API (Compliance date January 1, 2027)	Through cross reference to 42 CFR 422.119(c)(4) at 42 CFR 422.122(b)	Through cross reference to 42 CFR 431.60(c)(4) at 42 CFR 431.80(b)	Through cross reference to 42 CFR 431.80(b) at 42 CFR 438.242(b)(7)	Through cross reference to 42 CFR 457.730(c)(4) at 42 CFR 457.732(b)	Through cross reference to 45 CFR 156.221(c)(4) at 45 CFR 156.223(b)	



**TABLE H3: REQUIRED STANDARDS AND RECOMMENDED IMPLEMENTATION GUIDES TO SUPPORT API IMPLEMENTATION**

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



CMS finalized recommendations of specified IGs, listed as “recommended” in Table H3, which they encourage payers to use in addition to the required standards at 45 CFR 170.215.

CMS finalized standards for the Patient Access, Provider Access, Provider Directory, Payer-to-Payer, and Prior Authorization APIs. CMS also clarified that impacted payers will only be required to use the applicable standards and specifications identified as necessary for each API, the required standards are listed in Table H3.

CMS finalized its proposal to allow impacted payers to use updated standards, specifications, or IGs for each API under specific conditions. Impacted payers may only use updated standards under the following conditions:

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

CMS also finalized a modification to incorporate the expiration dates ONC adopted at 45 CFR 170.215(b)(1)(i) and (c)(1) since the CMS Interoperability and Prior Authorization proposed rule was published.