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

CMS-0057-P

Proposed Rule Summary

On December 6, 2022, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule imposing new requirements on Medicare Advantage (MA) organizations, Medicaid and the state Children's Health Insurance Program (CHIP) fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and qualified health plans (QHPs) in the federally-facilitated exchanges (FFEs). The proposals are designed to improve the electronic exchange of health care data and streamline prior authorization processes, while continuing to encourage interoperability in the healthcare market. Also in this rule, CMS proposes the addition of a new measure for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians under the MIPS Promoting Interoperability performance category. As has been the norm for most CMS rulemaking over the past few years, numerous requests for information are included.

The proposed rule is scheduled to be published in the *Federal Register* on December 13, 2022. **The 90-day public comment period closes on March 6, 2023.**

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I. Background and Description of Major Proposals

On May 1, 2020, CMS issued the Interoperability and Patient Access final rule[1] (CMS Interoperability and Patient Access final rule), under which CMS required affected payers to build and maintain APIs in order to increase patient access and data exchange and improve interoperability in health care. The API must conform with Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR) and meet other specifications.

CMS also published a proposed rule[2] on December 18, 2020 (December 2020 CMS Interoperability proposed rule) which built on provisions of CMS Interoperability and Patient Access final rule and applied to issuers of QHPs in FFEs, Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, and CHIP managed care entities. In that proposed rule, CMS proposed new requirements for state Medicaid FFS programs, state CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs to improve the electronic exchange of healthcare data and streamline processes related to prior authorization. Also, the Office of the National Coordinator for Health Information Technology (ONC) proposed the adoption of certain specified implementation guides (IGs) needed to support the proposed Application Programming Interface (API) policies in that proposed rule.

Many comments received in response to the December 2020 CMS Interoperability proposed rule objected that MA organizations were not included among the impacted payers. Other comments expressed concern about the proposed timeframes for implementation as well as the funding necessary to implement the requirements. The proposed rule was never finalized and is withdrawn in this proposed rule, which contains revised policies that were informed by comments to the December 2020 CMS Interoperability proposed rule.

The revisions under this proposed rule include applying the requirements to MA organizations and requiring impacted payers to use health information technology (IT) standards at 45 CFR 170.215 that are applicable to each set of API requirements proposed in the rule. CMS proposes a longer timeframe for implementation. Requirements would generally apply beginning in 2026, and there would be an exemption process for state Medicaid and CHIP FFS programs to seek an extension of proposed implementation deadlines, or an exemption from meeting certain proposed requirements, and an exemption process for issuers of QHPs on the FFEs.

Other proposals would be effective on the date of publication of the final rule; these include clarifications to Medicaid beneficiary notice and fair hearing regulations that apply to Medicaid

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

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

prior authorization decisions and proposed changes to terminology related to the Patient Access API.

This proposed rule would add a new "Electronic Prior Authorization" measure for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program and for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS. This is designed to move these participants in the healthcare market toward interoperability.

Several new requirements for prior authorization processes are proposed. These include requirements for all impacted payers to (1) implement and maintain a FHIR Prior Authorization Requirements, Documentation, and Decision API (PARDD API); (2) send information to providers regarding the specific reason for denial when a prior authorization request is denied, regardless of the mechanism used to submit the prior authorization request; (3) respond to prior authorization requests within certain timeframes (this requirement would not apply to QHP issuers on the FFEs); and (4) publicly report certain metrics about their prior authorization processes for transparency.

CMS states that the proposed rule includes policies intended to reduce payer, provider, and patient burden by improving prior authorization processes and helping patients remain at the center of their own care. One example relates to stakeholder concerns about the implementation of the payer-to-payer data exchange requirement finalized in the CMS Interoperability and Patient Access final rule; CMS proposes to rescind its previous payer-to-payer data exchange requirements and replace them with a new policy. The new policy would require impacted payers to build a Payer-to-Payer API to facilitate the exchange of patient information between payers, both at a patient's request and at the start of coverage with a new payer. Specifically, that data exchange would include all data classes and data elements included in a standard adopted at 45 CFR 170.213 (currently USCDI version 1), adjudicated claims and encounter data (not including provider remittances and enrollee cost-sharing information), and the patient's prior authorization decisions. Additionally, CMS now proposes to apply the newly proposed Payer-to-Payer API requirements to Medicaid and CHIP FFS programs.

For purposes of this summary, the terms "payer" and "impacted payer" are all-inclusive terms that refer to MA organizations, Medicaid and CHIP fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and QHPs in the FFEs. QHPs in FFEs exclude stand-alone dental plans and issuers only offering QHPs in the federally-facilitated Small Business Health Options Program Exchange (FF-SHOP) are not subject to this proposed rule. FFEs include Exchanges in states that perform plan management functions; state-based Exchanges on the Federal Platform are not FFEs.

Other terms used in the proposed rule are clarified. "Patient" is used throughout as an inclusive term although historically in some programs CMS has referred instead to "consumer," "beneficiary," "enrollee," or "individual." The term patient includes a patient's personal representative,[3] and could address policies in the proposed rule that require action by a patient. "Items and services" do not include prescription drugs or covered outpatient drugs.

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

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

CMS believe the proposals in this rule are aligned with its efforts to advance health equity for all because they may mitigate existing inefficiencies in policies, processes, and technology which affect many patient populations. An individual's ability to select an app of their choice when accessing their health information is cited as an example. Another example is a proposed requirement that impacted payers include information about prior authorizations in the data that are available through the Patient Access API and that they provide annual reports to CMS on certain metrics about patient data requests via the Patient Access API.

Requests for information are made on a number of general issues, including how the proposals could apply in the context of the Medicare fee-for-service (FFS) program; leveraging APIs to facilitate electronic data exchange between and with behavioral healthcare providers; improving medical documentation exchange among providers, suppliers, and patients; how using data standards and electronic health records can improve maternal health outcomes; and encouraging providers and payers to enable exchange under the Trusted Exchange Framework and Common Agreement (TEFCA) to make patient information more readily available for access and exchange in a variety of circumstances.

II. Provisions of the Proposed Rule

Unless otherwise stated, the proposed new requirements would be effective January 1, 2026. Unless noted otherwise, the payers impacted by this rule are Medicare Advantage organizations (MAOs), state Medicaid FFS programs, CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs.

A. Patient Access API

1. Background

The May 2020 Patient Access final rule required affected payers to give patients access to their own health information by sharing, via FHIR APIs, certain information, including patient claims, encounters with capitated providers (encounter data), and a subset of clinical data that patients can access via health apps. The December 2020 CMS Interoperability proposed rule is withdrawn, replaced by this new proposed rule that reflects stakeholder feedback. Once again, CMS proposes to require impacted payers to report Patient Access API metrics to CMS, but on an annual rather than quarterly basis. CMS seeks comment on a variety of privacy considerations, rather than the original proposal's requirement that impacted payers maintain a process for requesting an attestation from health app developers when the developers register their app with the payer's Patient Access API.

Although this rule does not directly pertain to Medicare FFS, CMS would implement these provisions so Medicare FFS beneficiaries could benefit from data availability. Specifically, CMS

would enhance Blue Button 2.0, which is a standards-based API that enables beneficiaries to access their Medicare claims data and view it through Medicare-authorized Blue Button apps. **CMS seeks comment on considerations for applying these requirements to Medicare FFS, if the proposals are finalized.**

2. Enhancing the Patient Access API

The 2020 Patient Access final rule required certain payers—MAOs, state Medicaid FFS programs, CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs—to implement and maintain APIs that permit enrollees to use health apps to access data specified at 42 CFR §§422.119, 431.60, 457.730, 438.242(b)(5), 457.1233(d), and 45 CFR §156.221, respectively. The Patient Access API must make available, at a minimum, adjudicated claims (including provider remittances and enrollee cost sharing), managed care encounters, and clinical data, including laboratory results, with a date of service on or after January 1, 2016, as maintained by the payer. As finalized, payers must make those data available via the Patient Access API no later than 1 business day after a claim is adjudicated or encounter or clinical data are received.

a. Prior Authorization Information

Under this proposed rule, information about prior authorizations would be added to the required categories of data through the Patient Access API. This includes all prior authorization requests and decisions for items and services (excluding drugs) for which the payer has data, and whether the decision is still pending, active, denied, expired, or is in another status. (Section II.D. summarizes proposed provisions to make the prior authorization process less burdensome for providers and payers.) Via the Patient Access API, impacted payers would make prior-authorization information available to patients not later than 1 business day after the payer receives the prior authorization request or there is another type of status change for the prior authorization (for example, approval or denial of a prior authorization request). Regardless of the impacted payer's terminology, the requirement to update the information available to the patient would generally apply to any meaningful change to the payer's record of the prior authorization request or decision. The required information would include the following:

- The prior authorization status,
- Date the prior authorization was approved or denied,
- If denied, the specific reason for denial as proposed in section II.D.4,
- Date or circumstance under which the authorization ends,
- Items and services approved,
- Quantity used to date under the authorization,
- Documentation including any materials that the provider sends to the payer to support a decision—for example, structured or unstructured clinical data including laboratory results, scores or assessments, past medications or procedures, progress notes, or diagnostic reports.

This proposal would enable patients to participate in their care more and reduce burden on both providers and payers, allowing them to more efficiently navigate the prior authorization process. Impacted payers would also be required to include this prior-authorization information via the

Provider Access API (section II.B.) and the Payer-to-Payer API (section II.C.) so that it is available to all relevant parties.

CMS believes 1 business day is also appropriate for prior-authorization information, as patients need timely access to understand the prior authorization processes and their available care options. As discussed in section II.D., payers would also be required to make much of the same information available during the decision-making process via the PARDD API. Information about prior authorizations would be available through the Patient Access API for as long as the authorization is active and at least 1 year after the last status change.

In addition to general comments on the proposed policies, CMS also requested comment on whether it should consider policies to require impacted payers to include information about prior authorizations for drugs (when the payer covers drugs) via the Patient Access API, the Provider Access API, and the Payer-to-Payer API, and how such future rulemaking through these APIs might interact with existing prior authorization requirements and standards.

b. Interaction with HIPAA Right of Access Provisions

Under the privacy rules based on the Health Insurance Portability and Accountability Act (HIPAA), patients generally have a right of access to obtain a copy of protected health information (PHI) about themselves in a designated record set (45 CFR §164.524). This rule would require payers to make that information available through a standards-based and interoperable Patient Access API. This would enable patients more access to their data through health apps, as they become more common, and reduce instances of an individual requesting electronic PHI (ePHI) in a format that is not readily producible.

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

CMS' proposals address how a payer must make patients' data available but does not have the authority to regulate the health apps that individuals use or what those apps do with PHI. However, other federal laws may apply, such as the Federal Trade Commission (FTC) Act—for example, if an app discloses an individual's health information in a manner inconsistent with the app's privacy policy.[4]

[4] For information about what laws may apply to health apps, see

c. Privacy Policy

CMS seeks to help ensure patients understand the implications of giving their health information to a health app, especially since CMS has no authority to directly regulate health apps. In the December 2020 Interoperability proposed rule, CMS proposed that impacted payers be required to request a privacy policy attestation from health app developers when their app requests to connect to the payer's Patient Access API. CMS proposed a number of specific content requirements on impacted payers' attestation from health app developers regarding their privacy policy.

Based on public comments and feedback, CMS is now concerned that those requirements would not benefit patients in ways that would outweigh the burden on impacted payers. The policy could have other unintended consequences for patients. For example, having payers inform patients that an app developer has attested to the form and format of a privacy policy could easily be misinterpreted as the payer (or CMS) having approved the substance of the privacy policy. Moreover, since CMS does not have statutory authority to regulate health apps, it cannot require developers to respond to the attestation, and the payer could not deny the app selected by the patient the requested access (unless it creates a security risk to the payer's own system). Commenters also expressed concerns that the proposed process would put an undue burden on payers to manage an attestation process for app developers with whom they have no legal or contractual relationship.

CMS requests comments on how, within the scope of its regulatory authority, it can help give patients the tools to understand the privacy and security implications of using a health app. CMS seeks ideas on how to balance the desire to educate patients with respecting their rights under the HIPAA Privacy Rule. For example, should payers be required to list apps accessing their API that comply with the transparency requirements of the Office of the National Coordinator for Health Information Technology (ONC) Model Privacy Notice (MPN)? CMS also requests comment on potentially leveraging the Trusted Exchange Framework and Common Agreement (TEFCA) (see additional information and RFI in section III.E.), the Common Agreement and Framework Agreement, and others described in the rule. CMS also requests comment on any actions that can ensure patients' equitable access to their health information, as well as the availability of apps accessible to individuals with disabilities, in a multitude of languages, and at an appropriate literacy level and in plain language.

d. Patient Access API Metrics

CMS proposes requiring payer to report metrics (aggregated and de-identified) to CMS on an annual basis about how patients use the Patient Access API. This data would help CMS evaluate if:

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

https://www.ftc.gov/business-guidance/resources/mobile-health-apps-interactive-tool.

The information would be required as follows:

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

CMS is considering and seeks comment on whether payers administering multiple plans under a single contract should be required to report data at the contract level. CMS also seeks comment on the benefits and drawbacks of the entities reporting data at higher levels (for example, at the parent organization level).

Based on feedback from the December 2020 proposed rule, CMS proposes to require reporting on an annual basis, rather than quarterly. The required information follows:

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

Payers would be required to report data from the previous calendar year by March 31—beginning for 2025 data by March 31, 2026. CMS does not plan to publicly report these metrics at the state, plan, or issuer level, but may reference or publish aggregated and de-identified data that does not include names of specific state agencies, plans, or issuers. **CMS seeks comment on this potential publication of aggregated data, as well as on what other Patient Access API metrics could be required or made available to the public on payers' own websites, for consideration in possible future rulemaking. CMS is also seeking comment on the potential benefits and burden of requiring payers to annually report the names of all the apps patients have used to access the payers' API.**

e. Patient Access API Amendments

Two minor terminology changes are proposed for the Patient Access API regulatory text applicable to each of the impacted payers. First, the existing requirement that APIs make available "clinical data, including laboratory results" would be replaced by "all data classes and data elements included in a content standard at 45 CFR 170.213" which is the USCDI version 1 and includes lab results immunizations, procedures, and assessment and plan of treatment. Second, in the text addressing denial or discontinuation of access to the API, the term "parties" would replace "enrollees" and "beneficiaries" as other parties may be accessing the APIs, such as providers and payers. These would go into effect on the effective date of the final rule.

f. Specific CHIP-related Regulatory Framework

CMS proposes to align separate CHIP managed care API requirements with Medicaid managed care API requirements (rather than CHIP FFS API requirements). Medicaid-expansion CHIP programs (that is, where a state uses its Medicaid program to cover CHIP-eligible children) would be subject to Medicaid rather than separate CHIP proposals in this rule.

3. Statutory Authorities for the Patient Access API Proposals

CMS reviews the rationale for the proposals made regarding the Patient Access API and the underlying statutory authority for each of the impacted payer types.

B. Provider Access APIs

1. Background

In the May 2020 Patient Access final rule, policies were implemented so the Patient Access API could allow patients to access their health information through an app and potentially share that information with their provider during an appointment. CMS sought comment on the feasibility of implementing and maintaining a FHIR API for data exchange between payers and providers and received comments strongly supportive of requiring data availability through a Provider Access API, including information about prior authorization decisions.

As in the December 2020 proposed rule (which is withdrawn), CMS again proposes to require impacted payers to implement and maintain a FHIR API to exchange data with providers. However, CMS is taking a different approach to the standards required, as described in section II.F. CMS is also proposing a patient opt-out (rather than an opt-in) policy, requiring payers to allow patients to opt out of the proposed Provider Access API. **Because these proposals do not pertain to Medicare FFS, CMS seeks comment on how the proposals, as described below, could be implemented in Medicare FFS.**

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

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

CMS proposes to require that impacted payers implement and maintain a Provider Access API to enable the information of current patients to be exchanged from payers to providers that are in that payer's network,[5] at the provider's request. Both the Provider Access API and the Patient Access API would use FHIR-based exchange of claims and encounter data, as well as all data classes and data elements included in the content standard at 45 CFR §170.213, such as immunizations, procedures, and assessment and plan of treatment. Both would also require payers to share information on prior authorization requests and decisions for items and services (excluding drugs).

To help providers gain efficient access to more comprehensive data on their patients, CMS proposes requiring impacted payers make available any of the applicable patient data with a date

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

of service on or after January 1, 2016, consistent with the Patient Access API as finalized in 2020. Thus, payers should already be maintaining and making available data from this timeframe via a FHIR API. Such disclosures would be permitted under the HIPAA Privacy Rule and other payer-specific laws and regulations, subject to limitations, reviewed by CMS in the rule.

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

Linking to the Patient Access API technical requirements, the Provider Access API would require adherence to the same technical standards, API documentation requirements, and standards for denial or discontinuation of access to the API. However, unlike for the Patient Access API, CMS is proposing to require the FHIR Bulk Data Access Implementation Guide at 45 CFR §170.215(a)(4). These requirements are described in greater detail in section II.F.

Unlike the 2020 proposed rule, this rule does not require payers to provide patient data to a provider that does not have a provider agreement or is not enrolled (in the case of Medicaid and CHIP FFS programs) with the payer holding patient's data—even though it may be permissible or even required by other law or regulation. CMS lists numerous privacy, security and program integrity concerns with such a requirement under the Provider Access API. Nevertheless, CMS encourages payers to share information via API with out-of-network or unenrolled providers who have a verified treatment relationship with the patient, to the extent permitted by law. **CMS seeks comment on various issues surrounding a possible requirement to provide out-of-network or unenrolled providers with access to their patients' information through the Provider Access API.**

CMS emphasizes that all data shared and received via this proposed data exchange would still have to be handled in a way that is consistent with all current and applicable laws and regulations, including HIPAA, and these proposals are not intended to modify those requirements. However, HIPAA transaction standards would not be applicable, since those only apply for exchanges requesting or issuing a payment.

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

Medicaid and CHIP plans and entities that are Non-Emergency Medical Transportation (NEMT) Prepaid Ambulatory Health Plans (PAHPs) would be exempt from the requirement to establish a Provider Access API, due to the unique nature and limited scope of the services these plans

provide. CMS does not believe that providers have a routine need for NEMT data. (These plans are also exempt from some managed care plan requirements in 42 CFR Part 438, but they must comply with the Patient Access API requirement. Section 438.9, which would be amended by this proposed exemption, identifies the regulations to which these plans are subjected.)

3. Additional Proposed Requirements for the Provider Access API

In general, the proposed requirements for the data and technical specifications that payers must follow as proposed in the Provider Access API align with the Patient Access API finalized in 2020 and proposed above. Additional proposed requirements for the Provider Access API follow, regarding attribution, patient opt-out process, patient resources, and provider resources.

a. Attribution

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

CMS encourages payers to use processes they may already have to attribute patients to their providers for various other purposes, including through health information exchanges (HIEs). As an example, CMS cites HL7's Da Vinci Member Attribution List FHIR Implementation Guide (IG), which defines various terms and describes a process for payers and providers to coordinate and reconcile their patient rosters under a particular payer-provider contract. CMS also points to the attribution process in its pilot project Data at the Point of Care (DPC), which is the Medicare FFS version of the Provider Access API and requires HIPAA-covered entities or their business associates to agree to certain terms of service before data can be sent to them. The current terms of service require organizations to maintain a list of patients being treated at their facilities, along with other requirements.

These requirements would apply beginning January 1, 2026 to MAOs, state Medicaid and CHIP FFS programs, Medicaid managed care entities other than NEMT PAHPs, CHIP managed care entities, and QHP issuers on the FFEs.

b. Opt Out

Unlike the 2020 proposed rule and the Payer-to-Payer API in section II.C, CMS proposes that all impacted payers would be required to have a process to allow patients or their personal representatives to opt *out* of having the patients' data available through the Provider Access API. (Under the 2020 proposed rule and the Payer-to-Payer API proposal, payers would have an opt-*in* process for patients.[6]) After weighing tradeoffs, CMS says its proposal defaulting to share data with providers, unless a patient opts out, appropriately balances the benefits of data sharing with the right of patients to control their health information. In response to the 2020 proposed rule,

[6] Opt-in policies require affirmative permission from a patient before their data can be shared. Opt-out policies allow their information to be shared unless the patient affirmatively revokes that permission.

commenters overwhelmingly supported an opt-out model, citing clinical and operational hurdles with an opt-in approach.

An opt-out by the patient would apply to all providers in the payer's network.

As with attribution, CMS is not being prescriptive in how the opt-out process is implemented. However, CMS anticipates payers would make this process available by mobile smart device, website, or apps, while also allowing mail, fax, or telephonic alternatives. Payers would have to make this opt-out process available (and give all currently enrolled patients or their personal representatives a chance to opt out) before the first date on which patient information is made available through the Provider Access API. Payers would also need a process to allow patients to opt back in. **CMS invites comments on whether it should establish more explicit requirements regarding patient opt-out processes, and whether patients should be able to exercise more granular control over which data they permit the payer to share (for example, from only specific timeframes).**

c. Patient Resources Regarding the Provider Access API

CMS proposed to require payers to do the following:

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

Although CMS is not proposing specific text or format for this information, it is requesting comments on whether this information should be provided in a specific format or to include specified content—particularly language on how patient data could be used and shared through the API.

d. Provider Resources Regarding the Provider Access API

Payers would be required to provide educational resources for providers on how to request access to patient data though the Provider Access API. The information would need to be provided on the payer's website and other appropriate provider communications. The resources would need to be in non-technical and easy-to-understand language.

4. <u>Extensions, Exemptions and Exceptions</u>

a. Extensions and Exemptions for Medicaid and CHIP FFS programs

CMS strongly encourages state Medicaid and CHIP FFS programs to implement the Provider Access API as soon as possible, if the proposals are finalized. However, because these agencies

may face circumstances not affecting other payers, including several examples provided in the rule, CMS proposes the following two opportunities.

Extension. An extension would come in the form of a written application as part of the state's annual Advance Planning Document (APD) for Medicaid Management Information System (MMIS) operations expenditures. The state Medicaid or CHIP FFS programs could request a one-time extension of up to 1 year for implementation of the Provider Access API.

The request would need to include the following:

- A narrative justification describing the reasons why the state cannot reasonably satisfy the requirement(s) by the compliance date, and why those reasons are unique to the agency (versus other types of impacted payers);
- A report on completed and ongoing state implementation activities that demonstrate a good-faith effort toward compliance; and
- A comprehensive plan to meet the Provider Access API requirements no later than 1 year after the compliance date.

An extension would be granted if CMS determines that the request establishes the need for delay and the state has a comprehensive plan to implement the proposed requirements no later than 1 year after the compliance date.

Exemption. Under the proposal, states could request an exemption from the Provider Access API requirements when at least 90 percent of the state's Medicaid beneficiaries are enrolled in Medicaid managed care organizations (MCOs) as defined in 42 CFR §438.2. This definition specifically refers to comprehensive managed care, thus excluding more limited state Medicaid managed care options such as PAHPs and prepaid inpatient health plan (PIHPs). According to 2019 data reported by MACPAC, 8 states had at least 90 percent of Medicaid enrollees in comprehensive managed care.

A similar exemption would be available for separate CHIP FFS—if at least 90 percent of the state's separate CHIP enrollees are in managed care entities (MCEs), as defined in 42 CFR §457.10. This CHIP definition of MCEs includes MCOs (that is, comprehensive coverage) as well as prepaid health plans and primary care case managers. Thus, the definitions between Medicaid and CHIP managed care for this purpose are not consistent.

This exemption opportunity is offered in this circumstance because the time and resources needed for the state to implement the Provider Access API requirements for a small FFS population may outweigh the benefits. CMS proposes that states granted an exemption would be expected to implement an alternative plan to ensure that providers have efficient electronic access to the same information through other means. CMS would grant the exemption if the state establishes to CMS' satisfaction that the state meets the criteria for exemption and has established an alternative plan.

The exemption would expire if either 2 of the last 3 years had managed care enrollment below 90 percent or CMS has approved a state plan amendment (SPA), waiver or waiver amendment that would significantly reduce the share of beneficiaries in managed care and that shift is confirmed

in data. States would be required to provide CMS with written notification if they no longer qualify for the Provider Access API exemption. The notice would be required within 90 days of finalizing the applicable data (Medicaid T-MSIS or CHIP Annual Report Template System (CARTS) report). For Medicaid FFS or CHIP FFS populations, the state would need to come into compliance of the Provider Access API requirements within two years of the exemption's expiration.

Although extension and exemption opportunities are not extended to Medicaid and CHIP managed care (for a number of reasons provided in the rule), CMS seeks comment on whether an extension process might be warranted and, if so, a number of related questions.

b. Exception for QHP Issuers

The proposed rule provides a possible exception to the Provider Access API proposal for QHP issuers on an FFE, parallel to the finalized exception process under the Patient Access API requirement. Under the proposed process the issuer would include as part of its application for QHP certification a request for an exception and provide a narrative justification describing why it cannot meet the requirements for the applicable plan year, the impact of non-compliance on providers and enrollees, current means of providing the information to providers, and solutions and a timeline for compliance. The FFE would be able to grant the exception if it determines that making the health plan available on the FFE is in the interests of individuals in the state.

5. Provider Access API in Medicaid and CHIP

If these proposals are finalized, states' Medicaid and CHIP program could access federal matching funds to implement the Provider Access API. States could receive the 50 percent federal match for administration. Ninety percent federal match could be available if expenditures could be attributed to the design, development, or installation (DDI) of Medicaid mechanized claims processing and information retrieval systems (1903(a)(3)(A)(i) of the Act). For the *operation* of Medicaid mechanized claims processing and information retrieval systems, 75 percent federal match could be available (1903(a)(3)(B) of the Act). CMS reviews the APD process for obtaining these funds.

For separate CHIP administrative expenses, states can obtain CHIP's enhanced federal medical assistance percentage (E-FMAP). However, administrative, outreach and certain other expenditures are limited to 10 percent of the state's annual CHIP spending (total computable expenditures).

For Medicaid expansion CHIP, the Medicaid requirements of these proposals would apply.

6. Statutory Authorities for Provider Access API

For each of the impacted payers, CMS discusses the statutory authority under which it is proposing the Provider Access API policies. It reviews the rationale for the proposals.

C. Payer-to-Payer Data Exchange on FHIR

1. Background

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

The 2020 Patient Access final rule required payer-to-payer data exchange, effective January 1, 2022 for MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. (Medicaid and CHIP FFS programs are not subject to this requirement.) This rule required that affected payers must maintain a process for the electronic exchange of the data classes and elements. Although the final rule did not specify an API standard, CMS encouraged payers to consider using a FHIR API and signaled it could be a future requirement.

Since then, payers have bemoaned the lack of technical specifications for the payer-to-payer data exchange and believe that it created implementation challenges, which resulted in poor data quality and increased administrative burden. CMS attempted to address this in the December 2020 proposed rule, which would have required use of a FHIR API. CMS is withdrawing that proposed rule and, for purposes of the payer-to-payer data exchange, proposes rescinding the applicable portions of the May 2020 final rule. CMS also has not been enforcing the payer-to-payer requirements of the May 2020 final rule, in accordance with the notice published in a Federal Register notice (86 FR 70412, December 20, 2021).

This rule again proposes requirements on impacted payers to implement and maintain a payer-to-payer data exchange using a FHIR API and a patient opt-in policy. However, the approach to standards is different than in the December 2020 proposed rule, as described in section II.F. below. As with almost all the policies in this proposed rule, the compliance deadline for the Payer-to-Payer API would be January 1, 2026.

CMS notes that each payer would only be responsible for its own side of a transaction. For example, if an impacted payer is required to request patient data from another payer that is *not* an impacted payer, the impacted payer must make that request regardless of the other payer's status. CMS is hopeful non-impacted payers will implement the Payer-to-Payer API.

For this portion of the rule, certain terms apply:

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

- Previous payers are where the patient previously had coverage and are responsible for sending data to the new payer. The term "previous payer" does not include Medicaid and CHIP agencies and managed care plans in the same state.

As with the other data exchanges in this rule, CMS is exploring steps for Medicare FFS to join in Payer-to-Payer data exchange. CMS says that, if these proposals are finalized, it intends to implement the Payer-to-Payer API capability to Medicare FFS. **CMS seeks comment whether this could be implemented for Medicare FFS as proposed and other related questions.**

2. Proposal to Rescind 2020 Patient Access Final Rule Payer-to-Payer Data Exchange Policy

The May 2020 Patient Access final rule required payer-to-payer data exchange, effective January 1, 2022, for MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. Based on concerns raised by stakeholders, CMS proposes to rescind the payer-to-payer data exchange policy in that final rule and replace it with policies proposed here. Unlike the previously finalized policy, CMS believes the proposed use of FHIR APIs would ensure greater uniformity in implementation and more complete information.

3. Payer-to-Payer Data Exchange on FHIR

a. Payer-to-Payer API Technical Standards

CMS now proposes the Payer-to-Payer API be built on the previously finalized standards, base content and vocabulary standards used for the Patient Access API and additional requirements proposed here for the Patient Access API (section II.A.2.) and Provider Access API (section II.B.2.). As with the Patient Access API, the proposed Payer-to-Payer API requires sharing all data classes and data elements included in a standard adopted at 45 CFR §170.213, adjudicated claims, and encounter data as well as the patient's prior authorization requests and decisions. These similar requirements should ease the API development and implementation process.

For the Payer-to-Payer API, CMS proposes requiring the use of certain implementation guides (IGs), referenced in existing 45 CFR §170.215 (and discussed in greater detail in section II.F.):

- OpenID Connect Core (45 CFR §170.215(b)) for authorization and authentication of the payer requesting data access through the API; and
- FHIR Bulk Data Access (Flat FHIR) IG (45 CFR §170.215(a)(4)) for exchanging multiple patients' data.

b. Payer-to-Payer API Data Content Requirements

The proposed content requirements for the FHIR Payer-to-Payer API consists of all data classes and data elements included in a content standard adopted at 45 CFR 170.213,[7] claims and encounter data (excluding provider remittances and enrollee cost-sharing information), and prior authorization requests and decisions with a date of service on or after January 1, 2016. CMS is

[7] The text of 45 CFR 170.213 says, "Standard. United States Core Data for Interoperability (USCDI), July 2020 Errata, Version 1 (v1) (incorporated by reference in § 170.299)."

excluding provider remittances and enrollee cost sharing information from Payer-to-Payer API data exchange because that information is often considered proprietary.

Required information includes any pending, active, denied, and expired prior authorization requests or decisions, as in the Patient Access API and Provider Access API. Again, this documentation would include the status of the prior authorization, the date the prior authorization was approved or denied, the date or circumstance under which the authorization ends, the items and services approved, and the quantity used to date. Leveraging proposed changes in section II.D., the specific reason for a prior authorization denial should also be included. Information about prior authorizations available through the Payer-to-Payer API would need to be available for the duration that the authorization is active and for at least 1 year after the prior authorization's last status change.

CMS is not proposing "at this time" to require payers to review, consider, or honor the active prior authorization decision of a patient's former payer, but believes payers may gain efficiencies by doing so. **CMS seeks comment on some of the considerations around sharing prior authorization data between payers, particularly for patients with specific medical conditions,** and highlights examples where using previous payer's prior authorization information can be beneficial to payers, providers and patients. **Because the new payer may not know the criteria used by the previous payer for its prior authorization decisions, CMS requests for possible future rulemaking on whether prior authorizations from a previous payer should be honored by the new payer and, if so, a number of related questions.**

c. Identifying Previous and Concurrent Payers and Opt In

CMS proposes that all impacted payers must develop and maintain processes to identify a patient's previous and/or concurrent payer(s). The proposal would also allow patients or their personal representatives to opt into payer-to-payer data exchange (both with previous and concurrent payers) prior to the start of coverage.[8]

Payers would be required to gather information about the patient's previous and/or concurrent payer(s) that would allow them to identify and request data from them, including the payer's name and a patient ID number.

Impacted payers would be required to allow a patient to report multiple previous and concurrent payer(s) and to request the patient's data from all previous and concurrent payers. Although CMS is not being prescriptive regarding the specific information obtained from patients, payers should collect only as much as necessary to identify previous and concurrent payers and to make a successful request. **CMS requests comments on which data elements are necessary or extraneous to make a Payer-to-Payer API request.**

[8] "Start of coverage" means when coverage begins or when the patient enrolls and benefits become effective. Some payers (for example Medicaid) may provide retroactive coverage, in which case the payer would need to have processes to collect permission from a previous or concurrent payer for Payer-to-Payer API data exchange prior to the date that the patient's enrollment is processed (not the effective date of the retroactive coverage).

No later than the compliance date for the Payer-to-Payer API (January 1, 2026), impacted payers would be required to establish and maintain a process to gather permission and identify previous and concurrent payer(s) from all currently enrolled patients. CMS suggests that payers use a soft launch, rolling implementation or a pilot before the compliance date.

For new patients, payers would be required to maintain a process for patients to opt in to the Payer-to-Payer API data exchange and to identify any previous and concurrent payer(s) before their coverage begins—for example, on Medicaid and CHIP applications. Payers would also be required to have a process for patients to opt in at any time after the start of coverage or, if they had opted in, to opt out at any time. **CMS seeks comment on incorporating proposed requirements into the FFE QHP enrollment process in current 45 CFR §156.265, which is not amended by this rule.**

CMS outlines reasons why it is proposing an opt-in approach for the Payer-to-Payer data exchange, but opt-out for the others in this rule. In short, the other data exchanges in this rule involve the patient's current payer and providers who are in the payer's network; however, because the payer-to-payer data exchange likely involves parties who do not have a direct relationship with each other, the patient should have a larger gatekeeping role. In addition, Medicaid and CHIP programs have requirements that prevent such an opt-out process—that is, sharing patient information with an outside source before obtaining permission from the individual or family. **CMS requests comments on the proposal for an opt-in process for gathering patients' permission for payer-to-payer data exchange and a number of related questions.**

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

CMS would require impacted payers to request a patient's data from a previous or concurrent payer no later than 1 week after the start of coverage. CMS consider this sufficient time for payers to complete the process of identifying patients' previous or concurrent coverage and to request data from those payers. If a patient opts in after the start of coverage and provider previous/concurrent payer information, the current payer would be required to request the data from the payer(s) no later than 1 week after the payer has the necessary permission and information, or the patient makes the request.

CMS generally expects this request to trigger a one-time data exchange. However, CMS wants to allow patients to request additional data exchange for outlier situations. In addition, data may be processed after the patient has transitioned to the new payer, making additional data available. CMS considered a policy to require additional data be sent to the new payer within 1 week of receiving it. **CMS seeks comment on whether such a policy would be beneficial or overly burdensome, listing other related questions.**

Besides requiring the use of OpenID Connect authorization and authentication protocols for authenticating identity of the requesting payer, the requesting payer would also be required to include an attestation with the data request, affirming that the patient has enrolled and opted in for the data exchange consistent with legal requirements. CMS recommends the use of certain

HL7 IGs, such as the HL7 PDex IG, which ensures both the technical and business processes of capturing and sharing a patient's permission for data exchange preferences are included in the payer-to-payer data request.

If the previous/concurrent payer is an impacted payer, it would be required to respond to a current payer's request within 1 business day of receipt. CMS believes this is the appropriate timeframe and aligns with the 1 business day response time for the Patient Access API and proposed Provider Access API.

CMS seeks comment on whether the proposed timeframes for a new payer to request patient data, and for the previous/concurrent payer to send these data, are appropriate or whether other timeframes would better balance the benefits and burdens. CMS asks whether payers could accommodate a shorter period for the data request at the start of coverage, such as 1 to 3 business days, and whether payers need more than 1 business day to respond to a request. If so, what is a more appropriate timeframe for payers to respond to data requests?

If a previous/ concurrent payer is not an impacted payer, they would not be subject to the proposed requirements and thus would not be required to send data through the proposed Payer-to-Payer API. For example, when a patient moves from a QHP on an FFE to an employer-based plan, the employer-based plan would not be impacted by this proposed requirement, and the new impacted payer would not be required to determine whether the previous payer is an impacted payer.

e. Data Exchange Requirements for Concurrent Coverage

An impacted concurrent payer would be required to collect information about any other concurrent payer(s) from patients prior to the start of coverage. A concurrent payer receiving an appropriate request would be required to send the same patient data described in section II.C.3.b. Such data exchange would be required within 1 week of the start of coverage with any concurrent payer reported by the patient. The receiving payer must then respond with the appropriate data within 1 business day of receiving the request.

Because patient records will continue to be updated with concurrent payers, impacted payers would be required to exchange the patient's data at least quarterly. **CMS considered other frequencies and requests comment on the appropriate frequency for payer-to-payer exchange for patients with concurrent coverage.**

f. Data Incorporation and Maintenance and Patient Education Requirements

Beginning January 1, 2026, payers would be required to incorporate information obtained through payer-to-payer data exchange into the patient's record.

Consistent with the proposed Provider Access API, payers would be required to provide patients with educational materials in non-technical, simple, and easy-to-understand language, explaining at a minimum:

- The benefits of Payer-to-Payer API data exchange,
- Patients' ability to opt in or withdraw a previous opt-in decision, and
- Instructions for doing so.

This would be required before requesting permission for the Payer-to-Payer API data exchange. The information would have to be provided annually to all covered patients in mechanisms the payer regularly uses to communicate with patients, as well as in an easily accessible location on the payer's public website. CMS requests comment on whether it would reduce payers' burden to only be required to provide these materials annually to any patients who have *not* opted in as well as those with known concurrent payers.

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

Medicaid and CHIP FFS programs were not included in the Patient Access final rule payer-to-payer data exchange requirement. CMS viewed it as potentially challenging for states to meet the required timeframe due to budget and resource constraints, and it wanted states to focus on meeting the Patient Access and Provider Directory API requirements.

Because it is now proposing that payers use a FHIR-based API for payer-to-payer data exchange, CMS believes that this requirement would not be as burdensome to states. By the time the proposed requirement would be in effect, Medicaid and CHIP programs must already have implemented the Patient Access API requirement, which makes this proposed new API less burdensome. CMS believes that the payer-to-payer API would make administration of Medicaid and CHIP more effective and reduce burden for patients and providers. For example, duplication of tests may be reduced.

CMS is proposing that if a Medicaid or CHIP agency is exchanging information under the Payer-to-Payer API proposal with a contracted managed care plan, the requirement to obtain patient opt-in would not apply. (The other proposed payer-to-payer requirements would apply, such as to use a FHIR API and the authorization and authentication protocols.) Medicaid and CHIP agencies already regularly exchange data with their managed care plans, and this Payer-to-Payer API proposal would not affect that ability. Medicaid and CHIP agencies and their contracted managed care plans use such exchanges to allow effective transitions between plans or delivery systems, to promote coordination and continuity of care. Current consent rules and requirements for Medicaid and CHIP are not affected by these proposals.

CMS is proposing that Medicaid and CHIP agencies (like all impacted payers) implement a process for current enrollees to opt in to payer-to-payer data exchange *prior to* the compliance date and prior to the enrollment of new beneficiaries *after* that date. State Medicaid and CHIP agencies, not their managed care plans, would be responsible for obtaining the required permission. Beneficiaries may switch between FFS and managed care delivery systems within the same state's Medicaid or CHIP program, but an eligible beneficiary remains a beneficiary of the state program. Thus, the beneficiary's permission to this data exchange should be obtained by

the state and would apply regardless of the delivery system. CMS understands this would require state agencies to create new processes to share a patient's opt-in preference with their managed care plans. Similarly, the requirement to identify patients' previous and/or concurrent payers would also apply to state Medicaid and CHIP agencies, not the managed care plans.

CMS considered not applying Payer-to-Payer API requirements regarding beneficiaries moving between coverage under Medicaid or CHIP. However, CMS is concerned many states do not exchange data between their FFS programs and managed care. **CMS requests comments on ways it can ensure patient data is exchanged in this case in a manner that would reduce burden on states. CMS also requests comment on the workflow and data exchanges that occur when a Medicaid or CHIP beneficiary is enrolled into managed care and the feasibility of including the patient permission during the enrollment process.**

CMS discusses the same potential for federal matching funds to support implementation of the Payer-to-Payer API as described above regarding the Provider Access API (section II.B.5.).

For Medicaid expansion CHIP, the Medicaid requirements of these proposals would apply.

5. Extensions, Exemptions, and Exceptions

For state Medicaid and CHIP FFS programs, CMS proposes opportunities for a one-time, one-year extension or an outright exemption from the Payer-to-Payer API requirements, as described in section II.B.5.a. above for the Provider Access API requirements.[9] For QHP issuers on the FFEs, an issuer may request an exception to the requirements for the Payer-to-Payer API under the same process discussed above with respect to QHIP issues on the FFEs for the Provider Access API (section II.B.4.b.).

6. Statutory Authority for Payer Exchange Proposals

For each of the impacted payers, CMS discusses the statutory authority under which it is proposing the Provider Access API proposals. It reviews the rationale for the proposals

D. Improving Prior Authorization Processes

1. Background

This section of the proposed rule includes several proposals related to prior authorization that are intended to improve the prior authorization processes for payers, providers, and patients. CMS uses the term prior authorization to refer to the process by which a provider must obtain approval from a payer before providing care in order to receive payment for delivering items or services. The following proposals are made with respect to impacted payers and are detailed further below. They would be required to do all of the following:

[9] As with the Provider Access API requirements, extensions and exemptions are not proposed for the Payer-to-Payer API requirements for Medicaid and CHIP managed care plans and entities.

- Implement and maintain a FHIR Prior Authorization Requirements, Documentation, and Decision API (PARDD API) API to support and streamline the prior authorization process;
- Respond to prior authorization requests within certain timeframes;
- Provide a clear reason for prior authorization denials; and
- Publicly report on prior authorization approvals, denials, and appeals.

The proposals would apply to any formal decision-making process through which impacted payers render an approval or denial determination in response to a prior authorization request based on the payer's coverage guidelines and policies before services are rendered or items provided. However, CMS clarifies that these proposed policies would not apply to any drugs that could be covered by the impacted payers, meaning any outpatient drugs, drugs that may be prescribed, those that may be administered by a physician, or that may be administered in a pharmacy, or hospital.

CMS notes that the proposals build on the CMS Interoperability and Patient Access final rule. It provides background on its development of these proposals, citing specific input from stakeholders through listening sessions, hearings, meetings, and reports. Stakeholders have emphasized that the variation in payer policies, workflow challenges and technical barriers all contribute to making prior authorization a major source of burden on providers and payers, a cause of provider burnout, and a health risk to patients when it causes a delay in needed care. CMS notes that numerous organizations conducted research and studies into improving payer prior authorization processes, with a focus on electronic prior authorization.

CMS modifies the name and description of the standards-based APIs intended to support prior authorization processes, but it did not change the purpose of those APIs. In this proposed rule, two of the previously proposed APIs in the December 2020 CMS Interoperability proposed rule are referred to collectively as the Prior Authorization Requirements, Documentation, and Decision (PARDD) API, which combines the functionality of the Document Requirement Lookup Service (DRLS) API and the Prior Authorization Support (PAS) API.

2. Electronic Options for Prior Authorization

Existing HIPAA transaction standards for the electronic exchange of information by covered entities include a prior authorization transaction standard (i.e., standards for referral certifications and authorizations). CMS notes that although payers are required to use to the X12 Version 5010x217 278 (or X12 278) standard for electronic prior authorization transactions, it has not achieved a high adoption rate by covered entities.[10] Payers instead build proprietary interfaces

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

and web portals through which providers submit their requests, and both still frequently resort to phone calls or faxes to complete the process for a response.

CMS believes enhancements to the electronic prior authorization process could support greater use of the HIPAA X12 278 standard through automation, which could also reduce the time for submission of the request and response. Thus, it proposes to require impacted payers to implement an HL7 FHIR API that would work in combination with the adopted HIPAA transaction standard to conduct the prior authorization process. CMS emphasizes that the proposal would not change the requirement for covered entities to use the adopted HIPAA transaction standard; rather, it would require that impacted payers develop and implement an API that works together with that standard, and may support greater use of the X12 278 standard.

CMS notes that new operating rules for the prior authorization standard are under consideration at HHS, but that the National Committee on Vital and Health Statistics (NCVHS) did not recommend that HHS adopt operating rules for the HIPAA referral certification and authorization transaction. Should NCVHS make a recommendation, CMS would evaluate their impact on the proposals in this rule.

In March 2021, HHS approved an application from an industry group of payers, providers, and vendors for an exception under 45 CFR 162.940 from the HIPAA transaction standards. The exception permits testing of proposed modifications to the prior authorization standard. Under this exception, the group would test a prior authorization exchange using the HL7 FHIR standard without the X12 278 standard, to determine whether this alternative standard for prior authorization could improve efficiency.

3. Proposed Requirement for Payers: Payers: Implement an API for Prior Authorization Requirements, Documentation, and Decision (PARDD API)

a. PARDD API

CMS proposes to require payers to implement and maintain a FHIR PARDD API to facilitate the prior authorization process for all prior authorization rules and requirements for items and services, other than drugs. Payers would have to comply with the requirement beginning January 1, 2026, or for Medicaid managed care plans and CHIP managed care entities, by the rating period beginning on or after January 1, 2026, and for QHP issuers on the FFEs, for plan years beginning on or after January 1, 2026. CMS considered but rejected a phased-in implementation schedule.

The proposals in this section are specific to the prior authorization process between payers and providers. CMS believes the PARDD API will streamline the process by automating some tasks. The API would allow providers to query the payer's system to see if prior authorization is required and the necessary documentation, and it would automate compilation of data required to populate the HIPAA-compliant prior authorization transaction and allow payers to provide the

status of the prior authorization request, including whether the request has been approved or denied.

CMS proposes to require the use of certain Implementation Guides (IGs) (adopted at 45 CFR 170.25) to implement the PARDD API. Impacted payers would have to use the same documentation requirements and the same discontinuation and denial of access requirements as are proposed for the Patient Access API, the Provider Access API, and the Payer-to-Payer API. If finalized, CMS also recommends using certain HL7 FHIR Da Vinci IGs, which are listed in this section of the preamble.[11]

The PARDD API would have to have the following functionalities:

- To be populated with the payer's list of covered items and services, excluding prescription drugs and/or covered outpatient drugs, for which prior authorization is required, and with the organization's documentation requirements for submitting a prior authorization request, including a description of the required documentation.
- To determine requirements for any other data, forms, or medical record documentation required by the payer for the items or services for which the provider seeks prior authorization, while complying with the HIPAA standard.
- To ensure responses from the payer to the provider include information regarding payer approval (and for how long) or denial (with a specific reason) of the request, or request more information from the provider to support the prior authorization request.

CMS believes that the PARDD API would make prior authorization requirements and documentation requirements more accessible and transparent to providers at the point of care. Providers could use the API to query the prior authorization requirements for specific items and services to identify documentation requirements and could use the API to complete electronic forms and templates or to link elsewhere to submit the documentation. The API would improve electronic data exchange between impacted payers and providers once provider practice management systems or EHRs connect with the API. CMS believes providers are eager to access this type of technology to replace the numerous web portals and fax numbers used to submit prior authorizations requests currently.

In addition, CMS sees benefits to payers because use of this API could reduce the number of unnecessary requests, minimize follow-up, and reduce denials and appeals. It notes that by the time the PAARD API would be required payers will have implemented the Patient Access API, and that infrastructure would provide the technology needed to support this proposed new API.

b. Federal Funding for State Medicaid and CHIP Expenditures on Implementation of the PARDD API

CMS discusses the potential for federal matching funds to support implementation of the PARDD APIs. For Medicaid this could be the standard 50 percent matching rate under section 1903(a)(7) of the Act or higher rates for expenditures related to developing and installing of

[11] These include the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide, the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR) Implementation Guide, and the HL7 FHIR Da Vinci Prior Authorization Support (PAS) Implementation Guide.

mechanized claims processing and information retrieval systems (90 percent) under section 1903(a)(3)(A)(i) of the Act or operating claims processing and information retrieval systems (75 percent) under section 1903(a)(3)(B) of the Act.

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

c. Medicaid Expansion CHIP Programs

CMS proposes for states with Medicaid Expansion CHIP programs that the proposals in this rule for Medicaid would apply to those programs rather than the proposals for a separate CHIP program. Functionally, the proposals are the same, but for clarity, CMS makes it explicit that the Medicaid requirements at §§431.60, 431.61, and 431.80 would apply to those programs rather than the separate CHIP requirements at §§457.730, 457.731, and 457.732.

4. Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations

a. Reason for Denial of Prior Authorization

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

b. Existing Program-Specific Notice Requirements for Prior Authorization Denial Information

Some payers that would be subject to the proposals in this rule are currently required to provide notice to patients or providers, or both, with the specific reasons for denial, under federal or state law. CMS notes that these proposals build on those existing policies, and that they would not modify or replace existing requirements to provide notice to patients, providers, or both.

For Medicaid managed care plans and CHIP managed care entities, CMS proposes that a response to a provider with respect to a prior authorization request, if transmitted via the PARDD API workflow process or other means, would satisfy current notice to provider requirements under 42 CFR 438.210(c). The responses could be whether the authorization request has been approved (and for how long), denied (with the reason for the denial), or a request for more

information to support the prior authorization. Payers would not have to send the response via both the PARDD API process and a separate, additional notice in another manner with duplicate information. However, payers would still have to provide a separate written notice to the enrollee.

MA program regulations specify the form and content of the written notice to enrollees in the event of an organization determination that results in a partial or full denial of items or services and the deadlines by which notice must be sent to both the enrollee and their physician. For MA organizations, CMS proposes that an organization determination would include an enrollee's request for prior authorization using the PARDD API in order to apply the policy proposals to MA organizations. Similarly, CMS proposes to apply the same policies regarding prior authorization processes that it proposes for MA plans and Medicaid managed care plans to applicable integrated plans[12] as well. The proposal would not change the content requirements for written denial notices to enrollees but would supplement them by requiring applicable integrated plans to notify the provider of the reason for a denial of a prior authorization request.

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

5. Requirements for Prior Authorization Decision Timeframes and Communications

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

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

CMS uses the term "standard" prior authorization to refer to non-expedited, non-urgent requests for prior authorization and the term "expedited" prior authorization to indicate an urgent request.

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

b. Proposals to Address Timeframes for Decisions on Standard and Expedited Prior Authorization Requests

CMS proposes to change the deadlines for prior authorization decisions as follows:

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

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

Current federal regulations impose a 72-hour deadline required for expedited decisions made by MA organizations, applicable integrated plans, Medicaid managed care plans, and CHIP managed care entities. The proposal would not change that policy nor would it impact the current authority for an extension of the deadline under those regulations. Additionally, CMS does not propose to change existing federal timeframes for standard and expedited determinations on requests for Part B drugs for MA organizations and applicable integrated plans.

For MA plans and applicable integrated plans, the timeframes would continue to apply to enrollee notices, and for Medicaid managed care plans and CHIP managed care entities, existing regulation requires that notices must be provided to both the provider and to the enrollee.

CMS does not propose to change timeframes for prior authorization processes for QHPs on the FFEs.

If the proposal is finalized, state laws that impose a shorter timeframe for these decisions would govern for Medicaid FFS, CHIP FFS, Medicaid managed care plans, and CHIP managed care entities. If, however, a state law imposes a longer time frame, payers could comply with both the federal and state regulations by complying with the shorter federal deadline. State laws do not apply to MA plans because of federal preemption rules in the statute and regulations; thus, MA plans would only be required to comply with timeframes set under federal regulation.

Comment is sought on a number of issues:

- What administrative, regulatory, technical, governance, operational, and workflow solutions would need to be addressed, for and by payers, to comply with the proposed timeframes for handling prior authorization review and approval activities?
- What operational or procedural changes payers or providers would need to make in their workflows or systems to reduce decision timeframes?
- Whether MA organizations, applicable integrated plans, Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities might be able to provide notice of standard and expedited prior authorization decisions within, for example, 5 calendar days and 48 hours, respectively, and if not, what specific issues and obstacles prevent that?
- Whether implementation of the proposed PARDD API could yield process improvements of sufficient magnitude to support shorter decision timeframe requirements for prior authorization requests?
- The anticipated operational challenges of implementing the API that might affect a payer's ability to meet the proposed timeframes.

- The costs, benefits, and operational impact on providers and payers, as well as the impact on patients, of making and communicating prior authorization decisions on a shorter timeframe than those proposed.

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

a. MA Organizations

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

CMS does not propose to change the current 72-hour decision timeframe for expedited requests or the availability of the 14-calendar day extension to make a determination for standard requests and for expedited requests. The lists of the regulation sections proposed to be amended is listed in Table 5 of the proposed rule.

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

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

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

Under current regulations, a state must provide an individual at least 10 days' notice prior to taking any action that includes termination, suspension, or reduction in benefits or services for which there is a current approved prior authorization and afford the beneficiary the right to continuation of services pending resolution of the state fair hearing. CMS proposes what it

describes as clarifying updates to the regulations to make it explicit that the existing Medicaid beneficiary notice and fair hearing rights apply to Medicaid FFS prior authorization decisions, independent of the notification timeframe proposed in the rule. These changes would apply as of the effective date of the final rule, but any notice or fair hearing right that is based solely on the new policies in this rule, if finalized, would take effect January 1, 2026.

CMS clarifies that the Medicaid beneficiary notice requirements at 42 CFR 435.917 and 431.210 through 431.214, including all proposed revisions and additions in the proposed rule, apply to the written notice provided by the state to the beneficiary. It also notes that current application of existing notice and fair hearing requirements to Medicaid FFS prior authorization decisions, including the proposed clarifications, is consistent with current regulations for notice and appeal rights for managed care prior authorization decisions. The sections of the regulations that CMS proposes to modify are listed in Table 6 of the proposed rule.

c. Medicaid Managed Care

Effective for rating periods that start on or after January 1, 2026, CMS proposes to require Medicaid managed care plans to provide notice of standard authorization decisions within state-established timeframes that may not exceed 7 calendar days following the plan's receipt of the request for service. It does not propose any changes to the timeframes for expedited decisions; however, it does propose to clarify that MCOs, prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) must make these decisions on shorter timeframes if the state requires shorter timeframes. As noted above, **CMS seeks comment on possible shorter deadlines for expedited decisions, such as 48 hours**. No changes are proposed to the current authority for the 14-calendar day extension to make a determination for standard requests and for expedited requests.

d. CHIP Fee-for-Service and Managed Care

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

CMS proposes to establish a federal maximum timeframe for prior authorization requests, and states with shorter deadlines could enforce those shorter timeframes for these requests.

e. QHPs on FFEs

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

Comments are sought on these proposed policies for notices and the timeframes for providing them.

7. Extensions, Exemptions and Exceptions

a. Extensions and Exemptions for Medicaid and CHIP FFS Programs

For state Medicaid and CHIP FFS programs, CMS proposes opportunities for a one-time extension or exemptions from the PARDD API requirements. The one-time extension would be for a period of up to year, and states would have to submit a written application, which should include the following:

- the specific reasons why the state cannot reasonably satisfy the requirement(s) by the compliance date and why those reasons resulted from circumstances that are unique to the state agency;
- a report on completed and ongoing state implementation activities showing a good faith effort toward compliance; and
- a comprehensive plan to meet the PARDD API requirements no later than 1 year after the compliance date.

Approval of an extension request would be based on whether the state sufficiently established the need to delay implementation and provided a comprehensive plan to comply with the PARDD API requirements by the end of the extension period. **CMS seeks comments on the proposal and whether it addresses unique state circumstances and whether it might make timely compliance with the proposed API requirement difficult for states**.

With respect to exemptions, CMS would permit state Medicaid FFS programs to request an exemption from the PARDD API requirements when at least 90 percent of the state's Medicaid beneficiaries are enrolled in Medicaid MCOs. Similarly, separate CHIP FFS programs would be able to seek an exemption from the PARDD API requirements if at least 90 percent of the state's separate CHIP beneficiaries are enrolled in CHIP managed care entities. The rationale for these exemptions is that state time and resource investments necessary to implement the API requirements would likely outweigh the benefits of implementing the API. States granted an exemption would have to implement an alternative plan to enable the efficient electronic exchange and accessibility of prior authorization information for those FFS beneficiaries to ensure that enrolled providers will have efficient electronic access to the same information available under the PARDD API through other means.

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

- Based on the 3 previous years of available, finalized Medicaid T-MSIS and/or CHIP CARTS managed care and FFS enrollment data, the State's managed care enrollment for 2 of the previous 3 years is below 90 percent; or

- CMS has approved a state plan amendment, waiver, or waiver amendment that would significantly reduce the share of beneficiaries enrolled in managed care and the anticipated shift in enrollment is confirmed by available, finalized Medicaid T-MSIS and/or CHIP CARTS managed care and FFS enrollment data.

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

Under both circumstances, the notice would have to be submitted within 90 days of finalization of the first annual Medicaid T-MSIS managed care enrollment data and/or the CARTS report for CHIP confirming that there has been the requisite shift from managed care enrollment to FFS enrollment.

If the exemption expires, the state would have to get CMS's approval of a compliance timeline for the PARDD API requirements for the state's Medicaid FFS and/or CHIP FFS populations within two years of the expiration date of the exemption.

CMS does not propose an extension or exemption process for Medicaid and CHIP managed care because the agency assumes that these entities are already developing the requisite infrastructure to comply with the proposed requirements. However, **CMS seeks comments on its assumption and whether it should provide for an extension for certain managed care plans (though the agency does not specify what types of plans it envisions for this purpose). If it decided to provide for such an extension process, it seeks feedback on a number of issues, including what criteria should it use to evaluate an extension request and which entity should evaluate the criteria (e.g., the state or some other entity)**?

b. Exception for QHP Issuers

CMS proposes to permit QHP issuers on the FFEs to request an exception to the requirements for the PARDD API as part of its application for QHP certification to be offered through an FFE. That request would have to include a narrative justifying the reasons why the issuer could not satisfy the requirements for the applicable plan year, the effect of that non-compliance on providers and enrollees, the current or proposed means of providing health information to providers, and solutions and a timeline to achieve compliance with those requirements.

FFEs would decide whether to grant or deny these exception requests. To grant a request for an exception, the FFE would have to determine that making the QHPs of the issuer available through such FFE is in the interests of qualified individuals in the state or states where the FFE operates, and an exception is warranted to allow the issuer to offer QHPs through the FFE. CMS notes that the proposal is consistent with the exception for QHP issuers on the FFEs that was finalized for the Patient Access API in the CMS Interoperability and Patient Access final rule.

8. Public Reporting of Prior Authorization Metrics

Impacted payers would be required to publicly report certain aggregated prior authorization metrics on their websites. For Medicare Advantage, reporting would be at the organizational level. For Medicaid and CHIP FFS programs, the reported data would be required at the state level. Reporting would be at the plan level for Medicaid and CHIP managed care and at the issuer level for QHP issuers on the FFEs.

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

- 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; and
- 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.

CMS is not proposing that payers report on categories of items and services, but rather aggregate the information as totals or percentages of total items and services. No specific format for how payers should present the aggregated data was proposed, but CMS encourages impacted payers to consider readability and accessibility. **It seeks comment from all stakeholders on how information might be displayed on payer websites, including the data that would be useful for patients**.

Under the proposal, beginning March 31, 2026, the data would be reported publicly annually, by the end of the first calendar quarter each year for the prior year's data. For example, for all impacted payers, all available data for calendar year 2025 would be publicly reported by the end of the first calendar quarter of 2026, or by March 31, 2026.

CMS believes that public reporting of this information would help inform patients and providers about payers. Patients may consider access to care in choosing a plan, and providers may consider information on prior authorization decisions useful when deciding whether to contract with a plan or join a network. **It seeks comment on its proposal, such as the types of data**

included in a report, the decision to report on an aggregate basis, the reporting timeframe, and the number of reports.

Table 7 in the proposed rule shows the sections of the regulations that would be changed by the proposed policies for impacted payer type.

9. Request for Comment on "Gold-Carding" Programs for Prior Authorization

CMS has previously sought comment on "gold-carding" or similar programs under which payers relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance with those payer requirements. CMS notes that under the MA program, organizations have the discretion to implement gold-carding programs within each contracted plan, and the agency itself uses a similar approach to gold-carding in the Medicare FFS Review Choice Demonstration for Home Health Services. It believes that gold-carding programs could help reduce provider burden related to prior authorization and facilitate more efficient and prompt delivery of health care services to beneficiaries.

CMS has encouraged payers to adopt gold-carding approaches that would allow prior authorization exemptions or more streamlined **reviews for certain providers who have demonstrated compliance with requirements. It seeks comments for potential future rulemaking on how to measure whether and how gold-carding or prior authorization exemption programs may reduce provider and payer burden, and improve services to patients and on how CMS and other payers could ensure that such programs benefit diverse populations**. The agency is considering including a gold-carding measure as a factor in quality ratings for MA organizations and QHPs, and **seeks comment on the idea**. It also considered proposing gold-carding as a requirement in payer's prior authorization policies, and **it seeks comment on how such programs could be structured to meet such a requirement**.

10. Statutory Authorities to Require Improvements in Prior Authorization Processes, Decision and Notification Timeframe Proposals

CMS reviews the rationale for the proposals made regarding prior authorization and the underlying statutory authority for each of the impacted payer types.

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

CMS proposes a new measure related to electronic prior authorization for MIPS eligible clinicians under the Promoting Interoperability (PI) performance category of MIPS, and for eligible hospitals and CAHs under the Medicare Promoting Interoperability Program (PIP). The new measure, entitled "Electronic Prior Authorization" would be included in the Health Information Exchange (HIE) objective for the MIPS PI performance category and in the HIE objective for the Medicare PIP. The measure is designed to address concerns over low provider utilization of APIs established by payers for electronic prior authorization, and CMS believes it

will further enable the electronic exchange of health information to improve the quality of healthcare, such as promoting care coordination.
Under the proposal, MIPS eligible clinicians would report this measure beginning with the CY 2026 performance period/CY 2028 MIPS payment year and eligible hospitals and CAHs would report the measure beginning with the CY 2026 EHR reporting period. However, the measure would not be scored in 2026. CMS notes that its proposed Electronic Prior Authorization measure would not alter a covered entity's obligation to use the HIPAA transaction standards required under 45 CFR 162.1302.

Under its proposal for the Electronic Prior Authorization measure, the healthcare provider would use data from their certified electronic health record technology (CEHRT), such as patient demographics and medical information, to justify the prior authorization request. The PARDD API would automate compilation of necessary data to populate the HIPAA-compliant prior authorization request. CMS notes that additional information not contained in CEHRT may also be required for submission, and the information would then be packaged into a HIPAA-compliant transaction for transmission to the payer. The following specifications are proposed for the Electronic Prior Authorization measure:

For MIPS eligible clinicians under the MIPS PI Performance Category—Electronic Prior Authorization

Measure Description: For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically from a PARDD API using data from CEHRT. The MIPS eligible clinician would be required to report a numerator and denominator for the measure or (if applicable) report an exclusion:

Denominator: The number of unique prior authorizations requested for medical items and services (excluding drugs) ordered by the MIPS eligible clinician during the performance period, excluding prior authorizations that cannot be requested using the PARDD API because the payer does not offer an API that meets the PARDD API requirements.

Numerator: The number of unique prior authorizations in the denominator that are requested electronically from a PARDD API using data from CEHRT.

Exclusion: Any MIPS eligible clinician who:
(1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; or
(2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the PARDD API requirements during the applicable performance period.

For Eligible Hospitals and Critical Access Hospitals in the Medicare PIP—Electronic Prior Authorization

Measure Description: For at least one hospital discharge and medical item or service (excluding drugs) ordered during the EHR reporting period, the prior authorization is requested electronically from a PARDD API using data from CEHRT. The eligible hospital or CAH would be required to report a numerator and denominator for the measure or (if applicable) report an exclusion:

Denominator: The number of unique prior authorizations requested for medical items and services (excluding drugs) ordered for patients discharged from the eligible hospital or CAH inpatient or emergency department (place of service (POS) code 21 or 23) during the EHR reporting period, excluding prior authorizations that cannot be requested using the PARDD API because the payer does not offer an API that meets the PARDD API requirements.

Numerator: The number of unique prior authorizations in the denominator that are requested electronically from a PARDD API using data from CEHRT.

Exclusions: Any eligible hospital or CAH that:
(1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable EHR reporting period; or
(2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the PARDD API requirements during the applicable EHR reporting period.

If a MIPS eligible clinician, eligible hospital or CAH fails to report the measure or claim an exclusion, with respect to a performance period or reporting period, as the case may be, they would not satisfy the MIPS Promoting Interoperability performance category or Medicare Promoting Interoperability Program reporting requirements, respectively, for that performance or reporting period. However, for CY 2026, a MIPS eligible clinician, eligible hospital, or CAH would be required to report a numerator of at least one for the measure or claim an exclusion, but the measure would not be scored. If the MIPS eligible clinician, eligible hospital, or CAH does not report a numerator of at least one for the measure or claim an exclusion, they would receive a zero score for the MIPS PI performance category or the Medicare PIP, respectively. A scoring methodology for the measure will be proposed in future rulemaking.

CMS notes that while the numerator only counts prior authorization requests made using the PARDD API and data from CEHRT, the denominator would also include prior authorization requests made using fax, mail, or portal to a payer that offers an API that meets the PARDD API requirements, even if that payer specifically requests a mailed or faxed prior authorization would be included in the denominator. Prior authorizations for drugs would be excluded from both the numerator and denominator of the measure.

With respect to the proposed second exclusion to the measure (i.e., only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets the PARDD API requirements during the applicable EHR reporting period), CMS considered but rejected an alternative under which a de minimis number of orders (such as 5 during the performance or reporting period) from a payer that does offer PARDD API would still qualify for the exception. **It seeks comment on the alternative it considered and whether**

another minimum number of prior authorization requests would be appropriate for the exclusion.

CMS also seeks comment on the following issues:

- Should it consider alternatives to the proposed numerator and denominator of the measure? Are there changes to these specifications that would reduce the implementation burden for both providers and health IT developers?
- What challenges will providers face in identifying those payers that have the PARDD API technology in order to accurately include eligible prior authorization requests in the denominator?
- What challenges will providers face in performing the actions included in the measure specifications and successfully reporting the measure if certification criteria are not available in the ONC Health IT Certification Program at the time providers are required to report the measure under the Medicare Promoting Interoperability Program or MIPS Promoting Interoperability performance category?
- With the understanding that ONC may consider policies in the ONC Health IT Certification Program that could further support this measure, are there alternate implementation timeframes that should be considered?

F. Interoperability Standards for APIs

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

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

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

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

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

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

With respect to IGs to support API requirements proposed in the rule, CMS had proposed in the December 2020 CMS Interoperability proposed rule requiring the use of FHIR IGs, including the CARIN IG for Blue Button®, HL7® FHIR® Da Vinci PDex IG, HL7® FHIR® Da Vinci PDex U.S. Drug Formulary IG, HL7® FHIR® Da Vinci PDex Plan Net IG, Da Vinci Coverage Requirements Discovery (CRD) IG, Documentation Templates and Rules (DTR) IG, and Prior Authorization Support (PAS) IG for this purpose. As noted earlier, that December 2020 CMS Interoperability proposed rule has been withdrawn and CMS declines to require the use of those standards. At this time, it only recommends their use, while acknowledging that it could limit interoperability. **It seeks comment on (1) whether in future rulemaking it should propose mandating the use of these IGs for previously finalized and proposed APIs and other ways to support innovation and interoperability, and (2) the process it should use to adopt or allow new versions of standards and implementation specifications over time**.

CMS proposes to require the use of API technology that conforms with the standards at 45 CFR 170.215 as applicable for each set of proposed API requirements. Table 8 in the proposed rule lists the regulation sections and requirements, and Table 10 identifies which standards would be required and which IGs are recommended for each proposed API.

III. Requests for Information

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

This RFI was included in the December 2020 CMS Interoperability proposed rule. Stakeholders asked for more time to comment, so CMS reissues the RFI with additional questions, which are shown in italic font.

As the use of value-based payment systems that emphasize whole person care have grown, interest in data on social risk factors has also increased. Social risk factors impact patient health, utilization, and outcomes, and these factors can have a direct impact on the healthcare system as a whole. To date, however, data on social risk factors is difficult to collect because of different formats, can be duplicative as different providers collect similar information from beneficiaries, and are difficult to integrate and utilize. Siloed social risk factor data may increase the burden on patients, as well as providers and the healthcare system overall by creating inefficiencies in managing referrals for social services and duplicative and conflicting workflows in an already strained system. Non-interoperable information flows may impede opportunities to provide higher quality care and result in missed opportunities to address the root causes of poor health outcomes and health inequities.

CMS seeks input on the barriers to using industry standards for social risk data collection and on opportunities to increase the adoption of such standards. Specifically, CMS asks:

- *What are best practices regarding frequency of collection of social risk and social needs data? What are factors to be considered around expiration, if any, of certain social needs data?*

- *What are best practices regarding workforce training on collecting social risk and social needs data? How could CMS best support such training?*

- What are the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools? How do these challenges vary across screening tools or social needs (for example, housing or food access)?

- What are the barriers to the exchange of social risk and social needs data across providers? What are key challenges related to exchange of social risk and social needs data between providers and community-based organizations? *CMS asks commenters to identify specific federal or other regulation, policy, or guidance and clarifying language that would be necessary to resolve the cited barriers.*

- What mechanisms are currently used to capture, exchange, and use social risk and social needs data (EHRs, HIEs, software, cloud-based data platforms, etc.)? What challenges, if any, occur in translating, collecting or transferring social risk data collected in these platforms to Z-codes on claims?

- How can payers promote exchange of social risk and social needs data? Are there promising practices used by public or private payers that can potentially be further leveraged in other settings?

- *What specific strategies, tactics, or policies would help CMS and other federal agencies facilitate greater standardization in the capture, recording, and exchange of social risk factor data? Are there best practices (related to contracting language, requirements in federal programs, etc.) that could be adopted, and by which agency?*

- *What are the most promising efforts that exist to date in resolving the challenges previously cited in this proposed rule? Which gaps remain that are not being addressed by existing efforts?*

- *What privacy issues should be considered when formulating policy for collecting and exchanging social risk and social needs data? Are there certain data elements that patients may wish to exercise more control over than others?*

- *What are best practices that are currently addressing other challenges previously cited in this proposed rule, such as integration of social risk and social needs data into clinical workflow, adoption, and use of commonly used screening tools with associated health IT standards and value sets, and integration of social risk data and social needs data into the patient's longitudinal health record?*

- *CMS asks stakeholders to identify potential existing, emerging, or possible new policy levers that it could use to better incentivize use and interoperability of social risk factor data as well as opportunities and approaches that would help the agency facilitate and inform effective infrastructure investments to address gaps and challenges for advancing the interoperability of social risk factor data.*

B. Electronic Exchange of Behavioral Health Information

This RFI was also included in the December 2020 CMS Interoperability proposed rule. Stakeholders asked for more time to comment, so CMS reissues the RFI with additional questions, which are shown in italic font.

CMS describes several factors that may have contributed to lower EHR adoption rates among behavioral health providers when compared to other types of providers. For example, the HITECH Act only made incentive payments for the adoption and meaningful use of certified EHR technology available to certain eligible professionals excluding many types of non-physician behavioral health providers. Also, regulatory requirements that govern the confidentiality of substance use disorder patient records maintained by certain entities, or more restrictive state laws, can also inhibit the exchange of behavioral health information.

Comments are sought on ways to support electronic data exchange of behavioral health information between and among behavioral health providers, other providers, and patients, as well as how to inform and support the movement of health data to behavioral health providers for

their use to inform care and treatment of behavioral health services. Specifically, CMS seeks comments on the following questions:

- Can applications using FHIR APIs facilitate electronic data exchange between behavioral health providers and with other health care providers and patients, without greater EHR adoption? What opportunities do FHIR APIs provide to bridge the gap? What needs might not be addressed by the use of applications with more limited functionality than traditional EHRs?

- *How can existing criteria under the ONC Health IT Certification Program ensure applications used by behavioral health providers enable interoperability? What updates to existing criteria, or new criteria, could better support exchange by these clinicians?*

- What levers could CMS use to facilitate greater electronic health data exchange among behavioral health providers? What are their associated costs, resources, and/or burdens?

- Are there particular considerations for electronic data exchange for behavioral health providers who practice independently, are community-based, are non-traditional providers, or are in rural areas? How could an API-based solution help address these considerations?

- Are there state or federal regulations or payment rules that have created barriers to technical integration of systems within these practices? What additional policy issues, technical considerations, and operational realities should be considered when looking at ways to facilitate the secure electronic exchange of health information maintained by behavioral health providers including sensitive health information?

- *What drivers at the federal, state, or local level currently support greater adoption of health IT for behavioral health providers? What new regulations, guidance, or other policy levers (including new authorities) could benefit community providers or include incentives for community providers to encourage greater adoption of health IT?*

- *What methods and approaches have stakeholders used to help advance health IT adoption among behavioral health providers, for instance, effective practices for braiding/blending of funds and as part of value-based models? How are stakeholders effectively strengthening system capacity, connecting to care, and creating healthy environments today?*

- *What privacy and security considerations would be the biggest barriers for community-based providers to engage in information exchange, and which could be addressed by federal policy, which by technology, and which by process?*

- What levers and approaches could CMS use to facilitate greater electronic health data exchange from and to community-based health providers including use of relevant health IT standards as feasible? What are their associated costs, resources, and burdens?

C. Request for Information: Improving the Exchange of Information in Medicare Fee for Service

As noted above, the HITECH Act only made incentive payments for the adoption and meaningful use of certified EHR technology available to certain eligible professionals, hospitals and CAHs excluding many types of providers and suppliers, such as home health agencies, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, and ambulance providers. This means that some providers and suppliers still use the U.S. Postal Service or fax machines to send patient information, which leads to delays in the receipt of orders, prior authorization decisions, and payments. Even where both the ordering and furnishing providers or suppliers use health IT to exchange information, the compatibility of the systems may not allow for the easy and/or expeditious exchange of that information. If prior authorization is required, disparities in health IT system data exchange capabilities could lead to delays in healthcare decision-making and potential delays in the delivery of care for patients.

CMS seeks comments on how Medicare FFS may support improvements to the exchange of medical documentation between and among providers or suppliers and patients, as well as how it may best inform and support the movement of health data (and its consistency) to providers or suppliers for their use to inform care and treat beneficiaries. It is also interested in what specific changes or improvements in health IT could assist providers or suppliers in submitting medical documentation to CMS and its contractors so that claims are not denied and/or are not deemed improper payments. Specifically, CMS seeks comments on the following questions:

- How might CMS encourage more electronic exchange of medical information (e.g., orders, progress notes, prior authorization requests, and/or plans of care) between providers and suppliers, and with CMS and its contractors, at the time an item or service is ordered? Are there specific process changes that would improve the exchange of medical documentation between ordering and furnishing providers or suppliers, and are there particular policy, technical, or other needs that must be accounted for in light of the unique roles of ordering and rendering providers or suppliers?

- Are there changes necessary to health IT to account for the need for providers and suppliers (ordering and furnishing) to exchange medical documentation, either to improve the process in general or to expedite processing to ensure beneficiary care is not delayed? How could existing certification criteria or updates to certification criteria under the ONC Health IT Certification program support specific exchange needs?

- What additional steps in health IT and the exchange of information could CMS take to assist providers or suppliers in the claim submission process? Are there changes in technology or processes that could also reduce the number of claims re-submissions and/or improper payments?

- What levers could CMS use to facilitate greater collaboration and exchange of information among providers and suppliers? What are the costs, resources, and/or burdens for this type of collaboration? Are there changes that could reduce improper

payments and the administrative burden of furnishing providers or suppliers who need medical record documentation from ordering providers or suppliers?

- Are there state or federal regulations or payment rules that are perceived as creating barriers to the exchange of information between ordering and furnishing providers or suppliers? What additional policy issues, technical considerations, and operational realities should be considered when considering ways to best facilitate the secure exchange of information between providers or suppliers and with Medicare FFS?

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

In July 2022, CMS published a maternity care action plan,[13] which aims to improve health outcomes and reduce disparities. It identified five key gaps in maternity care that relate to CMS programs: (1) coverage and access to care, (2) data, (3) quality of care, (4) workforce, and (5) social supports. It notes that technology may be leveraged to address known racial disparities to prenatal and postnatal care by facilitating telehealth visits or remote monitoring options. Some state Medicaid agencies used enhanced federal financial participation (FFP) to acquire remote monitoring and telehealth capabilities to address this inequity and expand access to remote blood pressure monitoring, behavioral health consultations, lactation consultations, blood glucose monitoring, etc. CMS seeks comments on how to further support these state efforts with that enhanced FFP system.

CMS wants to expand its data collection efforts, stratify data by key demographics to identify disparities in maternal care or outcomes, and coordinate across programs to identify gaps and best practices. For state Medicaid and CHIP agencies, the agency annually identifies a core set of measures for voluntary reporting that show the quality of care and health outcomes for those programs' beneficiaries, including the Maternity Core Set.[14] CMS believes that a critical foundation comprised of health IT, data sharing, and interoperability underlie many opportunities to improve maternal health outcomes. CMS seeks information from the public on evidence-based policies that leverage information technology to improve those outcomes.

CMS believes that using common data exchange standards for human services information may support maternal healthcare including by promoting greater information-sharing and interoperability, collaboration with other human services sectors beyond healthcare, and overall improvements to systems for the effective use of technology. It welcomes input on technical and policy approaches that link maternal human services data to health IT codes and value sets, such as ICD-10 and LOINC codes, to improve interoperability across multiple systems, domains, and use cases, including the effective use of interoperable assessment instruments. CMS seeks information on how other health IT standards, such as FHIR, can be used to expand healthcare

[13] Centers for Medicare & Medicaid Services. Cross-Cutting Initiative: CMS Maternity Care Action Plan. Retrieved from https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf.
[14] Centers for Medicare & Medicaid Services (2022). 2022 Core Set of Maternal and Perinatal Health Measures for Medicaid and CHIP (Maternity Core Set. Retrieved from https://www.medicaid.gov/medicaid/quality-ofcare/downloads/2022-maternity-core-set.pdf.

interoperability to integrate with human services for individual maternal health and overall population health improvement.

Noting that ONC launched an initiative called USCDI+ to support the identification and establishment of domain, or program-specific, datasets that build on the existing USCDI dataset, CMS believes the initiative could advance availability of maternal health information to meet federal partners' needs, such as by identifying and harmonizing data elements needed for quality reporting on maternal health measures under the Hospital IQR program.

CMS seeks feedback on the following questions:

- Are there other data elements and classes relevant to care coordination for maternal health that should be added to USCDI?

- Are there data related to maternal health that are currently not collected at scale, or not collected at all, that would be helpful for stakeholders to have access to? How could CMS support the collection of this data?

- What are key gaps in the standardization and harmonization of maternal health data? How can HHS support current efforts to address these gaps?

- How could an initiative such as USCDI+ be leveraged to harmonize maternal health data needed for care coordination, quality measurement, and other Federal programs that collect maternal health data?

With respect to prior authorization policies as applied to maternal care, CMS asks the following questions:

- Should there be special considerations for the prior authorization process in maternal healthcare? For example, should the timeframes for prior authorization be expedited in cases where the prior authorization is related to prenatal and perinatal care?

- How have prior authorization processes impacted maternal healthcare for patients enrolled in CMS programs?

- Should prior authorizations carry over from one payer to another when a patient changes payers for the duration of the pregnancy, or at least for a period of time while the patient and their provider gather the necessary documentation to submit a new prior authorization to the new payer?

- What other special considerations should be given to data sharing for maternal health transitions?

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

ONC is required by statute to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally," and it released the Trusted Exchange Framework[15] and Common Agreement for Nationwide Health Information Interoperability Version 1 (Common Agreement)[16] on January 18, 2022. The Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as Health Information Networks (HINs), care practices, hospitals, public health agencies, and Individual Access Services (IAS) providers. It also requires strong privacy and security protections for all entities who elect to participate, including entities not covered by HIPAA. In this RFI, the different modes of exchange by different stakeholders under this framework are referred to as "enabling exchange under TEFCA."

In the FY 2023 IPPS/LTCH final rule (87 FR 48780), a new, optional Enabling Exchange Under TEFCA measure was added to the Health Information Exchange Objective in the Medicare Promoting Interoperability program for eligible hospitals and CAHs. The CY 2023 PFS final rule (87 FR 70067) added a nearly identical measure for MIPS eligible clinicians as an alternative under the MIPS Promoting Interoperability Performance Category. CMS describes other efficiencies that could evolve through TEFCA, including as a catalyst for FHIR maturation and to support the availability of information through FHIR API exchange requirements such as those for the Patient Access API and the payer-to-payer API proposed in this rule.

Comment is sought on the following questions:

- How could the requirements of the Common Agreement and the Qualified Health Information Network (QHIN) Technical Framework Version 1 (QTF) facilitate information exchange under the final policies in the CMS Interoperability and Patient Access final rule around making clinical and administrative information held by health plans available to patients? How could TEFCA support proposed requirements for payers under this rule related to provider data access and prior authorization processes?

- How should CMS approach incentivizing or encouraging payers to enable exchange under TEFCA? Under what conditions would it be appropriate to require this approach by payers subject to the proposed regulations in this rule and previously finalized regulations in the CMS Interoperability and Patient Access final rule?

[15] The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (2022, January). HealthIT.gov. Retrieved from https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.
[16] Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022). HealthIT.gov. Retrieved from https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.

- What concerns do commenters have about potential requirements related to enabling exchange under TEFCA? Could such an approach increase burden for some payers? Are there other financial or technical barriers to this approach? If so, what should CMS do to reduce these barriers?

IV. Collection of Information

Under the Paperwork Reduction Act of 1995, CMS must provide 30-day notice in the *Federal Register* and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. HHS identifies provisions in the proposed rule for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995.

Overall, CMS has estimated that there are 365 parent organizations that would be impacted by the rules, if finalized. They are comprised of plans, entities, issuers, and state programs likely to be impacted by the proposals. They include:

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

Table 19 shows the total estimated burden across all impacted parent organizations is estimated to be $110 million in year 1; $221 million in years two and three, and $155 million in year 4, and $142 million for each subsequent year. Those cost estimates assume the following:

- The final rule will be published mid-year 2023 and the effective date will be January 1, 2026 for all provisions of that final rule.
- Table 19 reflects costs beginning in 2027, which is year 5 relative to mid-year 2023, the expected publication date for the final rule.
- Because the targeted publication date of the final rule is mid-year 2023, 2023 is treated as a half-year; thus, 2023 is one-half the costs expected to be incurred during 2024 and 2025.
- Implementation for the three new APIs would take place uniformly over 30 months (the time from the expected publication date for the final rule until the applicable compliance date in 2026).
- Maintenance costs for the three APIs are assumed to be 25 percent of total costs, which would be incurred in years 2026 and beyond.
- Policy updates or first-year implementation costs would take place in 2026, and subsequent year implementation costs would take place in years 2027 and beyond.
- No costs are reflected from 2023 through 2025 for the Electronic Prior Authorization measure.
- Labor costs in Table 19 are either BLS wages when a single staff member is involved or a weighted average representing a team effort, which is obtained by dividing the aggregate cost by the aggregate hours.

The burden estimate for the proposed reporting of Patient Access API Metrics to CMS is presented in Table 12, and it assumes this would be conducted in two major phases: implementation, including defining requirements and system design and updates to generate and compile reports; and maintenance, which includes compilation and transmission of annual reports to CMS. First year implementation costs are estimated to be $15,091 per impacted payer. Aggregate costs across all parent organizations are estimated to be $5.5 million. Ongoing maintenance could cost each organization about $3,013 per year for a total aggregated annual cost of $1,099,672.

The Provider Access API proposal would require three major work phases: initial design, development and testing, and long-term support and maintenance. CMS summarizes its estimates of the costs of the first two phases in Table 13. CMS prepared three estimates (low, median, and high estimates) for the first two phases, and the estimates reflected in this paragraph are the median or "primary" estimates from Table 13. One-time implementation efforts for the first two phases are estimated to cost $270,045 per organization with an aggregate burden across 365 parent organizations of $98.6 million. Ongoing maintenance costs are expected to be about one-quarter of the one-time API costs or $67,508 per parent organization – for a total of $24.6 million across all 365 parent organizations.

The Prior Authorization Requirements, Documentation, and Decision (PARDD) API Proposal would require three major work phases as well. CMS summarizes its estimates of the costs of the first two phases in Table 14. CMS prepared three estimates (low, median, and high estimates) for the first two phases, and the estimates reflected in this paragraph are the median or "primary" estimates from Table 14. CMS estimates one-time implementation costs for the first two phases of $1,144,444 per organization with aggregate costs across 365 parent organizations of $417.7 million. Ongoing maintenance costs are expected to be about one-quarter of the one-time API costs or $286,116 per parent organization – for a total of $104.4 million across all 365 parent organizations.

The per entity costs shown in Table 15 for the proposed modifications to the timelines for impacted payers to send prior authorization decisions is estimated to be $967 with a total burden of $353,028.

The requirement for public reporting of prior authorization metrics would require first-year implementation costs of an estimated $29,574 per organization with total costs across all 365 parent organizations of $10.8 million (see Table 16). For subsequent years, costs for each organization would average $9,041 with aggregate costs of $3.3 million.

Establishing the paper-to-payer API would require three work phases. CMS summarizes its estimates of the costs of the first two phases in Table 17. CMS prepared three estimates (low, median, and high estimates) for the first two phases, and the estimates reflected in this paragraph are the median or "primary" estimates from Table 17. For initial design and development, CMS estimates costs of $96,072 per organization for an aggregate across 365 parent organizations of $35.1 million. Ongoing maintenance costs are estimated to be $24,017 for each parent organization for an aggregate cost of $8.8 million.

For the proposal that MIPS eligible clinicians, eligible hospitals, and CAHs must report the Electronic Prior Authorization measure beginning with the CY 2026 performance period/EHR reporting period, Table 18 shows an estimated total cost of $1,740 for eligible hospitals and CAHs (4,500 hospitals and CAHs × ½ minute × $46.20 per hour) and an estimated total cost of $21,186 for MIPS eligible clinicians (54,770 clinicians × ½ minute × $46.20 per hour). Table 19 reflects costs beginning in 2027, which is year 5 relative to mid-year 2023, the expected publication date of final rule.

V. Regulatory Impact Statement

CMS examined the impact of the rules as required by Executive Order 12866 on Regulatory Planning and Review, the Regulatory Flexibility Act (RFA), the Unfunded Mandates Reform Act of 1995, Executive Order 13132, and Executive Order 13771.

Executive Order 12866 requires agencies to provide a regulatory impact analysis for all major rules with economically significant effects (of $100 million or more in any year). CMS estimates that the rule is economically significant and so has prepared a Regulatory Impact Analysis assessing the costs and benefits of the proposals.

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

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately $165 million. The proposed rule would not impose an unfunded mandate that would result in spending in any year in excess of the 2022 threshold of $165 million for a state, local or tribal government.

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

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

CMS expects that an increasing percentage of providers will participate in electronic prior authorization such that by 2034, 50% of all providers will participate. The burden associated with the existing prior authorization process is estimated to be $48,882 per individual and group physician practice per year. CMS assumes there are total of 199,543 individual and group physician practices, of which the MIPS eligible clinician practices affected by this proposed rule are a subset. It also assumes that all the 54,770 MIPS eligible clinicians would adopt the proposals of this rule in 2026 since there are payment consequences for them not doing so.

CMS believes the PARDD API proposal would make it possible for staff to use one system (such as their EHR or practice management system) or software application to find the prior authorization rules and documentation requirements for most impacted payers, compile the necessary data elements to populate the transaction, and provide the requisite documentation. Thus, it anticipates a reduction in prior authorization burden. CMS estimates physicians would reduce their time by 10 percent, registered nurses would have a reduction of 50 percent, and clerical would reduce their time by 25 percent. CMS estimates total savings of $14.7 billion in savings over the course of 10 years, as shown in Table 24. Adding hospitals burden reductions to the estimate would result in total savings of $15.3 billion over that 10-year period.

Total Costs of Proposed Rule. Overall, Table 27 estimates that the total costs of the proposed rule (excluding premium tax credit payments and savings from prior authorization) could range from $0.8 billion to $1.6 billion (in 2023 dollars).

Table 28 proposes ways for payers to defray some of the costs of the proposed rule. For example, CMS proposes that states could request extensions or exemptions from some of the proposed API provisions and that QHPs could absorb the costs or request an exception because they are a small commercial QHP issuer on the FFE. MA organizations in their bids would address the reduced rebates (arising from increased bid costs due to the increased costs of a final rule being included in the bid) by either: (1) temporarily absorbing costs by reducing profit margins; (2) reducing supplemental benefits paid for by the rebates; or (3) raising enrollee cost sharing (or reduce additional, rebate-funded benefits).

Alternatives Considered. CMS considered alternatives to the proposed provisions including:

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

clinical data, but determined that including claims and encounter data would allow for better care coordination and more efficient payer operations.

- A phased approach was considered for the proposal to implement the PARDD API, but CMS believes that it is less burdensome to require payers to populate these requirements for all items and services at the same time. CMS also considered requiring payers to post on a public website the items and services for which prior authorization is required, including their associated documentation rules, as an interim step but determined that this would not provide any reduced burden on payers or providers. **CMS seeks comment on whether a payer website to provide additional transparency to prior authorization requirements and documentation would be beneficial in reducing burden.** CMS also considered a phased timeline for implementation as well as alternative timelines for prior authorization decisions.
- CMS also considered several alternative timeframe policies for the completion of prior authorization decisions, but concerns were raised over the feasibility of implementing shorter timeframes.
- More frequent reporting of prior authorization metrics was also considered, but CMS concluded that its proposal is sufficient.

VI. Response to Comments

CMS states that it will consider all comments received by the deadline specified in the preamble (i.e., March 6, 2022) and that when it proceeds with a subsequent document, it will respond to the comments in the preamble to that document. It will not acknowledge or respond to all the comments individually.