Coppersmith Briefs

Expanded CMS Interoperability and Prior Authorization Requirements: What Payers, Providers and their Technology Vendors Need to Know

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On December 13, 2022, CMS published its revised proposed rule (CMS-0057-P) to expand and enhance interoperability mandates and prior authorization requirements (the "2023 Interoperability and Prior Authorization Proposed Rule").[1] **The comment period closes on March 13, 2023 at 5pm (EST).** This briefing provides impacted payers, health providers and their technology vendors with the information they need to know to comment on and prepare for these CMS interoperability mandates. **The proposed changes may take effect as soon as January 1, 2026, if finalized as proposed**.[2]

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What you might have missed: A little background on CMS' Policies and Technology for Interoperability and Burden Reduction

1. Phase One: The CMS Interoperability and Patient Access Final Rule

On May 1, 2020, CMS published its Interoperability and Patient Access Final Rule ("2020 Interoperability Final Rule"). The 2020 Interoperability Final Rule requires a select group of CMS-regulated payers—Medicare Advantage (MA) organizations, state Medicaid Fee-For-Service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid and CHIP managed care entities, and Qualified Health Plan (QHP) Issuers on the Federally Funded Exchanges (FFEs)[3] (collectively, "Impacted Payers")—to implement a Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR®)-based Patient Access API and Provider Directory API, and to participate in a Payer-to-Payer Exchange (but excluding state Medicaid and CHIP FFEs from P2P Exchange). APIs are interfaces (*e.g.* a set of commands, functions, protocols, or tools) that allow two systems—such as payer's system and a third-party application (app)—to communicate and share data securely. FHIR is a technology language that enables the systems to talk to each other and understand the data that is received.

CMS describes the 2020 Interoperability Final Rule as the "first phase" of fulfilling the promises of the Trump Administration's 2018 MyHealthEData Initiative by utilizing what CMS has learned through its operation of the Blue Button 2.0 Medicare program. The mission of the MyHealthEData Initiative is to ensure patients access to their health information and advance the seamless flow of health information within the health system. Blue Button 2.0 is CMS's Medicare program that offers Medicare members access to claims data through a third party application using a FHIR-based API. The Patient Access API and P2P Exchange requirements built on these initiatives by mandating Impacted Payers build and maintain APIs that facilitate individual access services and consumer-mediated use cases.

More specifically, the 2020 Interoperability Final Rule required Impacted Payers to give current members (and their personal representatives) access to a Patient Access API that allows them to, through the applications of their choice, easily access their claims and encounter information as well as clinical data, including laboratory results, and provider remittances and enrollee cost-sharing pertaining to such claims, if maintained by the Impacted Payer. The P2P Exchange, in turn, gives current and former members (and their personal representatives) the ability to direct their clinical data to their other health plans.

2. Phase Two: The Expanded and Enhanced Interoperability Proposed Rules

On December 18, 2020, CMS published is "second phase" of interoperability proposals—the "2020 Expanded Interoperability Proposed Rule." After an abbreviated comment period over the holiday season in 2020, the Trump Administration attempted to finalize the proposed rule change in January of 2021. But the rule was not published in the Federal Register prior to the Biden Administration's regulatory freeze and, effective March 17, 2021, CMS withdrew the 2020 Expanded Interoperability Proposed Rule, see RIN 0938-AT99.

However, CMS has leveraged the comments and feedback it received in response to the 2020 Expanded Interoperability Proposed Rule, and its experience in enforcing the 2020 Interoperability Final Rule, to inform its 2023 Interoperability and Prior Authorization Proposed Rule.

The 2023 Interoperability and Prior Authorization Proposed Rule builds on the 2020 Interoperability Final Rule by placing new requirements on Impacted Payers. **Unlike the 2020 Expanded Interoperability Proposed Rule, the 2023 Interoperability and Prior Authorization Proposed Rule includes MA organizations among the Impacted Payers subject to the proposed rule changes.** But like the 2020 Expanded Interoperability Proposed Rule, the 2023 Interoperability and Prior Authorization Proposed Rule is ground breaking because it goes well beyond giving patients control over their health information. It gives all key stakeholders in the health care ecosystems—patients, payers and providers—easy and ready access to a broad range of health information through a:

1. Patient Access API;
2. Payer-to-Payer (P2P) API (formerly known as, Payer-to-Payer Exchange); and
3. Provider Access API.

CMS also proposes to make changes to prior authorization requirements, including requiring Impacted Payers to build and implement a new prior authorization API. To encourage provider use, CMS proposes to add use of the prior authorization API as a new measure for its Promoting Interoperability program.

All of the APIs proposed in the 2023 Interoperability and Prior Authorization Proposed Rule require use of a FHIR API. We break down the API requirements and other proposed changes in greater detail below.

Changes to CMS Interoperability Mandates: Patient Access API, P2P API and Provider Access API

1. Patient Access API Data Expansion

The 2020 Interoperability Final Rule requires Impacted Payers to make the following types of data (with dates of service on or after January 1, 2016) accessible to current members and their personal representatives—using an application of their choice—through a FHIR API:

- Claims data (*i.e.*, adjudicated claims, including provider remittances and enrollee cost-sharing);
- Encounter data (*i.e.*, encounter data with capitated providers);
- Clinical data as represented in the U.S. Core Data for Interoperability, version 1 (USCDI v.1), if maintained in the member's record (including laboratory results); and
- In some instances, formulary data.

CMS refers to this interoperability mandate as the Patient Access API.

Starting on January 1, 2026,[4] the 2023 Interoperability and Prior Authorization Proposed Rule would require Impacted Payers to also make accessible through the Patient Access API any and all prior authorization data (excluding drugs) regardless of prior authorization status (*i.e.*, pending, active, denied, expired or any other status), including the associated information and documentation, within 1 business day after the Impacted Payer receives the prior authorization request or there is another type of status change for the prior authorization (*e.g.*, approval, denial, update with additional information/documentation, or change in item/service count). Impacted Payers must make such prior authorization data available for as long as the authorization is active and at least 1 year after the last status change. CMS is not proposing to require that Impacted Payers share a member's full prior authorization history, as it would constitute a significant amount of information that may no longer be clinically relevant.

The prior authorization data must include all of the following data elements and documentation:

- The prior authorization status;
- The date the prior authorization was approved or denied;
- If the prior authorization was denied, the specific reason for the denial;
- The date or circumstance under which the prior authorization ends;
- If applicable, the items and services approved and the quality/units used to date; and
- Any materials that the provider sends to the payer to support a decision, including structured or unstructured clinical data including laboratory results, scores or assessments, past medications or procedures, progress notes, or diagnostic reports.

CMS also proposes to require Impacted Payers to report annual metrics to CMS about patient use of the Patient Access API. Specifically, CMS proposes to require Impacted Payers to submit confidential reports containing the following aggregated, de-identified data:

- The total number of unique patients who use the Impacted Payer's Patient Access API to transfer their data to a health application; and
- The total number of unique patients whose data is transferred more than once using the Patient Access API.

Depending on the volume of transactions, such metrics may be difficult for Impacted Payers to produce if they use the same API audit logs to track use of an API for Patient Access API and the P2P API. Thus, Impacted Payers should design their API connections to separately log and track API uses cases. The first metrics will be due by March 31, 2026, and must cover report data from the previous calendar through March 31.

Notably, CMS abandoned its proposal in the 2020 Expanded Interoperability Proposed Rule to require payers to employ a collection and notice process for applications (or apps) to attest to certain privacy and security practices prior to accessing member data. Such a process will remain optional, but it is not required. Additionally, Impacted Payers are still required to make educational resources available to members about protecting the privacy and security of their health information, including factors to consider in selecting an apps (such as potential secondary uses of data); the importance of understanding an app's security and privacy practices; an overview of which types of organizations or individuals are

and are not likely to be HIPAA-covered entities; and the oversight responsibilities of the Office for Civil Rights (OCR) and the Federal Trade Commission (FTC), and how to submit a complaint to those entities.

CMS also seeks comment on:

- Within their regulatory authority, how best to provide patients with information about app security and privacy practices, how to leverage Office of the National Coordinator of Health Information Technology's (ONC's) Model Privacy Notice and how CMS might leverage other health information exchange initiatives (*e.g.*, ONC's Trusted Exchange Framework and Common Agreement (TEFCA), which requires individual access service (IAS) providers to meet stringent privacy and security requirements);
- Whether Patient Access API metrics should be publicly released and whether the proposed metrics are sufficient. More specifically, CMS is interested in feedback regarding whether Impacted Payers should report aggregated demographic information, such as sex, race, age, ethnicity, and geographical (for instance, by zip code) data to help identify disparities or underserved populations, and the potential benefits and burden of requiring Impacted Payers to report the names of all apps that members have used each year;
- Whether CMS should required Impacted Payers to include prior authorization data for drugs via the Patient Access API, as well as the P2P API and Provider Access API discussed below; and
- Whether and how it should apply similar Patient Access API requirements on Medicare FFS.

2. Payer-to-Payer (P2P) API, including Bulk Data Access

In the 2020 Interoperability Final Rule, CMS required Impacted Payers—but excluding state Medicaid and CHIP FFS programs—at a member's request, to exchange electronically the clinical data they maintain in current and former member records with the members' other payers (the "Payer-to-Payer Exchange" or "P2P Exchange"). While CMS encouraged the use of a FHIR-based API for P2P, it did not require use of FHIR API in the 2020 Interoperability Final Rule. CMS permitted any method of electronic exchange. However, this lack of technical standards created challenges to implementation, which if not corrected, could lead to incompatible implementations across the industry, poor data quality, operational challenges, and increased administrative burdens. Consequently, CMS announced enforcement discretion for this policy in December of 2021, until the technical implementation challenge could be addressed in future rulemaking.

The 2023 Interoperability and Prior Authorization Proposed Rule proposes to address the implementation challenge by rescinding the current P2P Exchange in its entirety and requiring use of a FHIR API for P2P by January 1, 2026;[5] hence the name change to P2P API. CMS is specifically requiring use of the Implementation Guides (IGs) adopted under 45 CFR 170.215 for P2P, including OpenID Connect Core for authorization and authentication. Impacted Payers will also be required to use the HL7 FHIR Bulk Data Access (Flat FHIR) IG to support exchange for groups of members.

CMS is proposing to keep the "opt in model" for P2P API. CMS has rejected the "opt out model" on the ground that specific statutory and regulatory requirements applicable to state Medicaid and CHIP programs require use of the opt in model. Specifically, CMS interprets 42 CFR 431.306(d) and 42 CFR 457.1110(b) as prohibiting Medicaid and CHIP

programs from sharing beneficiary information with outside sources (such as other payers) before obtaining permission to do so from the individual or family.

CMS further proposes to:

- Extend the policy to Medicaid and CHIP FFS programs (which were previously excluded from the P2P Exchange), but permit Medicaid and CHIP FFS programs and QHP issuers on the FFEs to apply for an extension, exemption, or exception, as described in greater detail below;
- Require that claims and encounter data (but not remittances and member cost-sharing information), as well as prior authorization data, be made accessible via the P2P API. This is the same data that Impacted Payers must make accessible via the Provider Access API;
- Require that Impacted Payers develop and maintain processes to identify a patient's previous and/or concurrent payers and to allow members (or their personal representatives) to "opt in" to P2P API (*i.e.*, get permission). CMS proposes that the identification and opt in process occur prior to the start of coverage (*e.g.*, when the patient enrolls and benefits become effective) and, for state Medicaid/CHIP agencies, during the application/enrollment process or some later point prior to the start of coverage (such as through an online portal or application). CMS further proposes that the state Medicaid/CHIP agencies—rather than the managed care plans—bear the responsibility for obtaining and managing the identification and permission process because they are the primary custodian of the member's record;
- Require, if the patient opts in to P2P API, that Impacted Payers request a member's data from their previous and/or concurrent payer(s) no later than 1 week after the start of coverage;
- Require, if the patient opts in to P2P API and identifies the payer(s), or otherwise requests data exchange for another reason after the start of coverage, that Impacted Payers make the data request no later than 1 week after the Impacted Payer has the necessary permission and information or the patient makes the request;
- Require that requesting payers include an attestation with the request for data affirming that the patient has enrolled with the requesting payer and has opted in to the data exchange in a manner that meets the necessary legal requirements;
- Require that Impacted Payers that receive a request for data exchange respond within 1 business day;
- Require that Impacted Payers that provide concurrent coverage to a member who has opted into P2P API share data quarterly; and
- Require Impacted Payers to provide to members—in an easily accessible location on its public website—non-technical, easy to understand education materials about the benefits of the P2P API, and instructions for how to opt in and how to opt out after opting in. These materials must be provided annually to all covered members in mechanisms that the payer regularly uses to communicate with members, as well as at or before requesting opt in to P2P API.

Impacted Payers who receive P2P data would be required to incorporate the data into the member's record and thus also make it accessible through the receiving payer's Patient Access API, Provider Access API and P2P API. However, CMS does not propose to require Impacted Payers to retain records after disenrollment. CMS is also not proposing to require

Impacted Payers to specifically review or act on the data received. Nor are Impacted Payers required to rely on a prior or concurrent payer's prior authorization determination. As CMS previously explained in the preamble to the 2020 Interoperability Final Rule, receiving payers could choose to indicate which data were received from a previous payer so a future receiving payer, provider, or patient, would know where to direct questions (such as how to address contradictory or inaccurate information).

CMS further proposes to extend the following extensions, exemptions and exceptions to the P2P API:

- Medicaid FFS and CHIP FFS programs may request a one-time ***extension*** of up to 1 year to implement P2P API;
- Medicaid FFS programs may request an ***exemption*** from P2P API when at least 90% of the state's Medicaid beneficiaries are enrolled in Medicaid managed care organizations.
- CHIP FFS programs may request an ***exemption*** from P2P API when at least 90% of the state's separate CHIP beneficiaries are enrolled in CHIP managed care entities.
- QHP issuers on the FFE may seek an ***exception*** as part of the application process if it believes it cannot meet the proposed requirements.

State FFS programs that qualify for an ***exemption*** must have an alternative plan in place to ensure that other payers will have efficient electronic access to the same information through other means. They must also notify CMS in writing if enrollment shifts such that they no longer qualify for the exemption (*i.e.*, if enrollment falls below 90% for two out of three years).

CMS seeks comment on the following:

- Whether P2P API could be implemented for Medicare FFS;
- Whether prior authorizations from a previous payer should be honored by the new payer, and if so, whether time or condition limitations should be imposed;
- Whether CMS should continue to require a member opt in model for this data sharing or make further regulatory changes to the Medicaid and CHIP confidentiality requirements to support an opt out model;
- Whether CMS should require more than a one-time data exchange and, if so, with what frequency;
- Whether there are other state or federal privacy or security laws that the P2P API implicates;
- Whether to change the timeframes for responding to P2P API requests under different circumstances;
- How the workflow could be structured to obtain member permission (opt in) and identification of concurrent coverage during the Medicaid or CHIP enrollment process; and
- Whether an extension process would be warranted for certain managed care plans and, if so, what that process and evaluation criteria would look like.

3. Provider Access API, including Bulk Data Access

Beginning on January 1, 2026,[6] CMS proposes to require Impacted Payers to build and maintain a new Provider Access API for payer-to-provider data sharing with in-network providers (who have a treatment relationship with current plan members) for the same data in the expanded Patient Access API (but excluding remittances and member cost-sharing

information) for both individual patient requests and groups of patients (*i.e.*, bulk data access). The same look back period used for Patient Access API would also apply; that is, the covered data maintained by the Impacted Payer with a date of service on or after January 1, 2016, must be made accessible through the Provider Access API.

Unlike the Patient Access API and P2P API, which are both consumer-mediated, the Provider Access API will be provider mediated; that is, the in-network provider who has the treatment relationship with the patient will initiate the data exchange through the providers' EHR, practice management system, HIE connection or other provider system. The Provider Access API would thus allow providers—without patient involvement—to request the same type and scope of data accessible to patients in the Patient Access API (but excluding cost information) for patients to whom they currently provide care or are planning to provide care. This is also the same type and amount of data that would be accessible through P2P API for members' other payers.

The 2023 Interoperability and Prior Authorization Proposed Rule for Provider Access API is also notably different from the proposal in the 2020 Expanded Interoperability Proposed Rule in a couple of significant ways. Specifically:

- In-Network Providers Only. CMS proposes to limit the Provider Access API requirement to in-network providers only. There is no longer a proposal to extend this mandate to out-of-network providers. However, CMS strongly encourages this data sharing to the extent permitted by applicable law.

- Opt Out Process. CMS is also proposing to require Impacted Payers to implement a process to allow patients to opt out of the Provider Access API. This is a change from the 2020 Expanded Interoperability Proposed Rule, in which CMS proposed an opt-in process. Unlike P2P API, CMS interprets the Medicaid and CHIP regulations as permitting use of an opt out process with in-network providers because they are not outside sources for which family or individual permission is required. Under the proposed opt out model, Impacted Payers must make educational resources available to patients that describe the benefits of participating in the Provider Access API, their right to opt out, and instructions for how to opt out and opt-back-in to Provider Access API. This education must be expressed in nontechnical, simple, and easy-to-understand language, and provided at enrollment and at least annually thereafter. It must also be posted in an easily accessible location on the Impacted Payers' public websites. Members must have the option to opt out before the first date on which their information is made available via the Provider Access API and at any time while the member is enrolled with the Impacted Payer. CMS does not prescribe the opt out mechanism, but anticipates that Impacted Payers will make the process available to members via mobile smart device, website, applications, mail, fax, and telephonic methods.

But similar to the earlier proposed rule, CMS continues to propose:

- To exclude Non-Emergency Medical Transportation (NEMT) and Prepaid Ambulatory Health Plans (PAHP) from the Provider Access API requirements;
- To permit certain Impacted Payers—state Medicaid and CHIP FFS programs and QHP issuers on the FFEs—to apply for an extension, exemption, or exception, as applicable, from implementing the proposed Provider Access API, as discussed in greater detail below; and

- To require that Impacted Payers provide health care providers with education materials about the Provider Access API. Similar to the patient education materials, the provider-facing materials must be non-technical, easy-to-understand, and available on the payer's website and other appropriate provider communications.

It is unclear whether CMS intends to limit provider access to the Provider Access API for treatment and care coordination purposes, or if it will also support other use cases, such as payment or certain HIPAA-permitted health care operation activities. This is an open question because CMS expressly states that the HIPAA transactions will not apply to the Provider Access API because "the purpose of the exchange would not be to request or issue a payment."[7]

The Provider Access API—like the other CMS mandated APIs—must be implemented consistent with other applicable health information privacy and security laws, like the HIPAA, 42 CFR Part 2 and more stringent state laws. Impacted Payers should consider commenting on whether it is feasible to support provider access for use cases other than treatment in compliance with applicable state and federal health information privacy and security laws, including but not limited to HIPAA and 42 CFR Part 2. CMS also emphasizes that it is the Impacted Payer's responsibility to verify the identity and authority of the provider requesting access. To that end, CMS proposes requiring Impacted Payers to have an attribution process to ensure that the data is shared only with providers who have a treatment relationship with the patient. For example, CMS suggests Impacted Payers generate a current patient roster using claims data, and only permit data exchange through the Provider Access API to providers with whom those patients can be attributed via claims data or for which the provider can demonstrate proof of an upcoming appointment. CMS also suggests use of an attestation process whereby providers agree in the terms of service to maintain a list of patients being treated at their facilities and attest that they have a treatment-related purpose for adding a patient to their group.

With respect to extensions, exemptions and exceptions, CMS proposes to give state Medicaid or CHIP FFS agencies a mechanism by which to seek a:

- One-time ***extension*** for up to 1 year from the compliance deadline due to resource challenges (like funding); or
- One year ***exemption*** (per calendar year) from these proposed requirements if 90% state's Medicaid beneficiaries are enrolled in Medicaid managed care organizations, or 90% of Medicaid/CHIP beneficiaries are enrolled with Medicaid or CHIP managed care organizations. States granted an exemption must implement an alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means. Such exemptions would expire if a state's managed care enrollment for 2 of the previous 3 years is below 90%. CMS proposes to require states to provide CMS with written notification if they no long qualify for an exemption.

CMS similarly proposes an ***exception*** for QHP Issuers on the FFEs as part of its QHP application, in which the QHP Issuer must include as part of its QHP application a narrative justification describing the reasons why it cannot satisfy the requirement, the impact of non-compliance upon providers and enrollees, the current or proposed means of providing health information to providers, and solutions and a timeline to achieve compliance with the Provider Access API requirements. Like the extension offered for the Patient Access API in the 2020 Interoperability Final Rule, CMS expects

to grant it only for QHP Issuers on the FFEs that are only in the individual or small group market, financially vulnerable, or new entrants to the FFEs who demonstrate that compliance would pose a significant barrier to their ability to provide coverage and that not certifying the issuer's QHP would result in too few or no plan options in certain areas.

Finally, CMS seeks comment on:

- Whether to apply the Provider Access API to Medicare FFS;
- Whether to expand application of the Provider Access API to out-of-network (OON) providers in future rulemaking. CMS specifically seeks comments on how payers could verify that OON providers have a treatment relationship with the patients;
- Processes for attributing patients to in-network providers who have a treatment relationship with the patient, especially in cases of new patient-provider relationships;
- How to implement the opt out process and whether it is technically feasible to allow patients to opt out at the provider-level (as opposed to a global opt out); and
- Whether an extension process should be offered to Medicaid managed care organizations and, if so, what the criteria should be.

Changes to the Prior Authorization Requirements

CMS also proposes to make changes to prior authorization requirements for item and services, including a new FHIR Prior Authorization Requirements, Documentation, and Decision (PARDD) API and changes to timing and content requirements. Prior authorization refers to an administrative process by which health care providers seek approval from health plans to provide health care items or services to patients. This process happens prior the provision of such items and services, and thus can become a health risk for patients if there are inefficiency delays. The process also varies widely from plan to plan and is an often cited reason for provider burnout. Notably, the proposed changes will not directly impact Medicare FFS; however, CMS seeks comment on whether the PARDD API should be implemented for Medicare FFS. **The proposed prior authorization changes will also not apply to drugs of any type, including 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**. That's because the prior authorization requirements that apply to drugs are different from those that apply to items and services.

1. The Prior Authorization Requirements, Documentation and Decision (PARDD) API

In an effort to address the inefficiency and patient safety issues with the current prior authorization process, CMS is proposing to require Impacted Payers to build and deploy a single Prior Authorization Requirements, Documentation and Decision (PARDD) API, which must be ready for go live by January 1, 2026. CMS further proposes to require Impacted Payers to use certain IGs adopted at 45 CFR 170.215 and recommends (but does not require) use of certain HL7 FHIR Da Vinci IGs.[8] The PARDD API requirement will functionally take the place of CMS's previously proposed, separate APIs for document requirement lookup services (DRLS) and prior authorization requests (PAS).

The PARDD API is intended to automate the entire prior authorization process, starting with whether a prior authorization is required, what information and documentation is required, and the exchange of those prior authorization requests, supporting information and documentation, and decisions from the provider's EHR or practice management systems. CMS envisions the following functionality:

- A provider will query the payer's system to determine whether a prior authorization is required for an item or service.
- The API will then query the payer's prior authorization documentation requirements and make those requirements available within the provider's workflow, as well as support the automated compilation of necessary information from the provider's electronic system (*e.g.*, the EHR or other administrative system) to populate a prior authorization transaction from the provider to the payer. HIPAA standard transaction requirements for prior authorizations (X12 278 version 5010) are still required for covered entities. Thus, the PARDD API may need to communicate through an intermediary, such as a clearinghouse, to convert the FHIR request to a HIPAA-compliant standard transaction.
- Finally, the payer will communicate to the provider via the PARDD API whether the request has been: (1) approved and for how long; (2) denied and, as discussed below, the specific reason for the denial; or (3) whether more information is needed to support the request.

CMS proposes to extend the following extensions, exemptions and exceptions to the PARDD API:

- State Medicaid FFS and CHIP FFS programs may request a one-time ***extension*** of up to 1 year to implement the PARDD API;
- State Medicaid FFS programs may request an ***exemption*** from the PARDD API if at least 90% of the state's Medicaid beneficiaries are enrolled in Medicaid managed care organizations;
- CHIP FFS programs may request an ***exemption*** from the PARDD API if at least 90% of the state's CHIP beneficiaries are enrolled in CHIP managed care entities; and
- QHP issuers on the FFE may seek an ***exception*** as part of the application process if it believes it cannot meet the proposed requirements.

State FFS programs that qualify for an ***exemption*** must have an alternative plan in place for the efficient electronic exchange of prior authorizations. They must also notify CMS in writing if enrollment shifts such that they no longer qualify for the exemption (*i.e.*, if enrollment falls below 90% for two out of three years).

Provider use of these FHIR APIs will be voluntary. However, CMS is proposing a new prior authorization measure for eligible clinicians, hospitals and critical access hospital (CAHs) under the relevant CMS Promoting Interoperability programs.[9] Specifically, CMS proposes to include an "Electronic Prior Authorization" measure in the existing health information exchange (HIE) objective measure starting with the 2026 performance/reporting periods. To meet the measure, a prior authorization must be requested electronically from a PARDD API using data from certified EHR technology (CEHRT). Under this proposal, these eligible clinicians, hospitals, and CAHs would be required to report the number of prior authorizations for medical items and services (excluding drugs) that are requested electronically from a PARDD API using data from CEHRT. CMS is seeking comment on whether eligible clinicians, hospital and CAHs that

request a small number of prior authorizations—such ≤ 5 prior authorizations—may claim an exclusion from this measure.

CMS also seeks comment on:

- Whether the January 1, 2026 go live date for the PARDD API should be replaced with a phased functionality approach, such as making prior authorization rules and documentation requirements available incrementally; and
- Whether an extension process should be considered for Medicaid and CHIP managed care.

2. Other Proposed Prior Authorization Changes

CMS also proposes the following changes to the prior authorization requirements:

- **Denial Reason (starting January 1, 2026):** CMS proposes to require Impacted Payers to include the specific reason for a denial (such as missing documentation, medical necessity, exceeded limits, *etc.*), regardless of whether the PARDD API or another method is used to send the prior authorization decision. The intent is to boost transparency in the prior authorization process for patients, regardless of the technology used. This requirement is also in addition to (and not a replacement of) existing state and federal laws that require payers to notify providers and patients when adverse decisions are made.

- **Shorter Prior Authorization Timeframes (starting January 1, 2026):** CMS proposes that MA organizations and applicable integrated plans, Medicaid FFS programs and CHIP FFS programs must send prior authorization decisions within 72 hours for urgent (expedited) requests and a maximum 7 calendar days for non-urgent (standard) requests (or fewer if state law establishes a shorter timeframe). For Medicaid and CHIP managed care entities, CMS is proposing a maximum 7 calendar days for standard requests and is not proposing to change the required timeframes for expedited decisions, which are already set at no later than 72 hours after receipt of the request for service. In fact, CMS is seeking comments on whether it should shorten the proposed timelines further to 48 hours and 5 calendar days, respectively, and what administrative, regulatory, technical, governance, operational, and workflow solutions would need to be addressed, for and by payers, to comply with the proposed timeframes. CMS is not proposing to change timing requirements under existing federal law for Part B drugs for MA organizations (*i.e.*, no later than 72 hours for standard determinations and 24 hours for expedited). CHS is also not proposing to change the availability of any extensions or current regulatory consequences for payer failure to meet required timeframes.

- **Prior Authorization Metrics (starting March 31, 2026)**: CMS further proposes to require Impacted Payers to publicly report annually aggregated data about the prior authorization process on their websites, such as a lists of all the items and services that require prior authorization; the percent of standard prior authorization requests approved and denied; and average time between submission and determination. The goal is to improve transparency and accountability for plans. CMS is also seeking comment for future rulemaking on how CMS could measure whether "gold carding"—the practice of relaxing or reducing prior authorization

requirements for providers that have demonstrated a consistent pattern of compliance—reduces administrative burden and improves services to patients.

Standards and Implementation Guides

As noted above, CMS requires use of API standards that conform with ONC's health information technology (IT) standards set forth at 45 CFR 170.215, including the HL7 FHIR standard, the HL7 US Core IG, and HL7 SMART Application Launch Framework IG. In the 2020 Interoperability Final Rule, CMS established a voluntary process for Impacted Payers interested in using updated versions of those standards. CMS proposes to apply this process to all of the CMS mandated APIs—Patient Access API, P2P API, Provider Access API, and the PARDD API—and emphasizes that when using updated standards, a Impacted Payer must continue to support connectivity for end users and may only use an updated version if it does not disrupt a user's ability to access the data available through the API.

Notably, since the 2020 Interoperability Final Rule, the ONC has released several updated standards through the Standards Version Advancement Process (SVAP) process that may be used by Impacted Payers to meet CMS' interoperability mandates, including the following:

- USCDI (Version 2);
- HL7 FHIR® US Core Implementation Guide (Version 4.0.0 and Version 5.0.1);
- HL7 FHIR® SMART Application Launch Framework Implementation Guide (Release 2.0.0); and
- HL7 FHIR® Bulk Data Access (Flat FHIR®) (v2.0.0: STU 2).

As noted above for P2P API and PARDD API, CMS in some instances is also requiring (or considering requiring) use of other industry IGs in addition to those required by 45 CFR 170.215. More generally, however, CMS is not requiring use of specific IGs. Instead, CMS is "strongly recommending payers use certain IGs."[10] At this time, CMS is specifically recommending the following IGs:

- 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 CRD IG, DTR IG, PAS IGs; and
- The IGs listed on Table 10 in the 2023 Interoperability and Prior Authorization Proposed Rule.

CMS will wait until these IGs are further developed and refined before mandating use.

Additional Requests for Information

Lastly, CMS is seeking comment on future rulemaking concerning the following topics not otherwise described above:

- **Accelerating the Adoption of Standards Related to Social Risk Factor Data.** CMS seeks input on how to standardize social determinants of health (SDOH) data and encourage the SDOH data exchange.

- **Electronic Exchange of Behavioral Health Information.** CMS seeks comment on how APIs could serve as a solution for data exchange with behavioral health providers who are behind in EHR adoption and might not use CEHRT.

- **Improving the Electronic Exchange of Information in Medicare Fee-for-Service (FFS).** CMS seeks comment on how CMS can support efforts to improve clinical data exchange among ordering providers/suppliers and rendering providers/suppliers of health care items and services in Medicare FFS. Similar to behavioral health providers, other types of providers such as home health agencies, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, and ambulance providers are behind in EHR adoption.

- **Advancing the Trusted Exchange Framework and Common Agreement (TEFCA).** In 2022, ONC released the first version of the Trusted Exchange Framework and Common Agreement or TEFCA. ONC and the Recognized Coordinating Entity (RCE)—the Sequoia Project—are in the process of vetting, approving, onboarding and testing the first batch of qualified health information network (QHINs) that will provide the technical background for nationwide, TEFCA-based data exchange. CMS seeks comment on how CMS can incentivize or encourage payers to enable exchange under TEFCA. This is an excellent opportunity to request that CMS recognize a presumption that payer participation in a TEFCA network demonstrates the payer's compliance with the Patient Access API, Provider Access API and P2P API requirements.

- **Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health.** CMS also desires comment on how CMS could improve maternal health outcomes by using data policies (such as USCDI) and interoperability mandates.

Want to Learn More?

If you are interested in learning more about current and proposed CMS interoperability requirements, please visit the following sites:

- 2023 Interoperability and Prior Authorization Proposed Rule
- CMS, Policies and Technology for Interoperability and Burden Reduction
- CMS, Fact Sheet: Advancing Interoperability and Processes Proposed Rule CMS-0057-P
- CMS, FAQs on 2020 Interoperability and Patient Access Final Rule

About Coppersmith Brockelman and the Authors

Coppersmith Brockelman is working with health plans and technology vendors on compliance with the CMS interoperability requirements, as well as other laws affecting how health plans handle electronic health information

internally and externally, including the Information Blocking Rule, HIPAA, 42 CFR Part 2 and other state and federal privacy and security laws. Please do not hesitate to contact us for assistance with this new and developing area.

Melissa Soliz is a leader in compliance with data privacy, patient access and interoperability laws (such as HIPAA, 42 CFR Part 2, the ONC Information Blocking Rule, the CMS interoperability mandates, and state laws), health information exchange networks and exchange (HIN/HIE), behavioral health/substance use disorder law issues, data breaches and OCR investigations, as well as clinical research compliance and contracting. Melissa regularly speaks in local and national forums on these topics and has been active in state and federal policy making on data privacy and health information exchange issues. She is the President of the Arizona Society of Healthcare Attorneys and is recognized for her work in health law as a 2022 Phoenix Business Journal Top Lawyer, Best Lawyers© and Southwest Super Lawyers: Rising Stars©.

Viki Prescott represents health care systems, health technology vendors, hospitals, clinics, academic medical centers, and research institutes in matters of data sharing and privacy, clinical research, biobanking, and related regulatory compliance. She regularly assists clients in the negotiation of complex agreements, such as clinical trial contracts, health information exchange participation agreements, research collaborations, software and technology development, and licensing. Viki has technical and legal experience in software and international background in all types of intellectual property law. Viki has been active in national health care policy and has advised on proposed state and federal legislation.

By the way, you know the Coppersmith Briefs are not legal advice, right? Right! Check with your attorney for legal advice applicable to your situation.

ENDNOTES

[1] 87 FR 76238 (Dec. 13, 2022).
[2] There are some clarifying changes to existing Medicaid beneficiary notice and fair hearing regulations, which apply to Medicaid prior authorization decisions, and to terminology in the Patient Access API regulations that if finalized will take effect immediately.
[3] Please note that QHP Issuers on the FFEs exclude issuers offering only stand-alone dental plans (SADPs); QHP issuers offering only QHPs in the Federally-facilitated Small Business Health Options Program Exchanges (FF-SHOPs); and State-based Exchanges on the Federal Platform (SBE-FPs).
[4] Starting January 1, 2026 means the following for the different Impacted Payers: 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.
[5] Starting January 1, 2026 means the following for the different Impacted Payers: 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.
[6] Starting January 1, 2026 means the following for the different Impacted Payers: 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.
[7] 87 FR at 76257-58.
[8] Specifically, the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide; HL7 FHIR Da Vinci Documentation Templates and Rules (DTR) Implementation Guide; and HL7 FHIR Da Vinci Prior Authorization Support (PAS) Implementation Guide.
[9] CMS' Promoting Interoperability programs include the Merit-Based Incentive Payment System (MIPS) and the Medicare Promoting Interoperability Program.
[10] CMS, Fact Sheet: Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule CMS-0057-P: Fact Sheet (Dec. 6, 2022).