Coppersmith Briefs

CMS Proposed Expansion of Interoperability Requirements for Impacted Payers

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CMS has released a proposed rule that would significantly expand application programming interface (API) requirements for certain CMS-regulated health plans and impose new requirements for prior authorizations. **The comment period closes on January 4, 2021 at 5pm (EST).** This briefing provides impacted payers and other interested stakeholders with the information they need to know to respond within this unprecedentedly short comment period to what CMS rightly describes as a "watershed moment."[1]

2020 CMS INTEROPERABILITY AND PATIENT ACCESS FINAL RULE

On May 2, 2020, CMS published its CMS Interoperability and Patient Access Final Rule ("Interoperability Final Rule"). The Interoperability Final Rule requires a select group of CMS-regulated payers—Medicare Advantage (MA) organizations, Medicaid Fee-For-Service (FFS) programs, CHIP FFS programs, Medicaid and CHIP managed care entities, and Qualified Health Plan (QHP) Issuers on the Federally Funded Exchanges (FFEs) (collectively, "Covered 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 the Payer-to-Payer Exchange). APIs are interfaces 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 that enables the systems to talk to each other and understand the data that is received.

CMS describes the Interoperability Final Rule as the "first phase" of fulfilling the promises of the Trump Administration's 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 patient 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.

CMS PROPOSED EXPANSION OF API REQUIREMENTS FOR 2023

On December 10, 2020, CMS released its "second phase" of interoperability proposals—the Expanded Interoperability Proposed Rule. The proposed rule was officially published in the Federal Register on December 18, 2020, and CMS held a public listening call about the proposed rule on December 16, 2020.

The Expanded Interoperability Proposed Rule builds on the Interoperability Final Rule by placing new requirements on certain CMS-regulated payers—state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP Issuers on the FFEs ("Impacted Payers"). **The Expanded Interoperability Proposed Rule requirements will not apply to Medicare Advantage (MA) organizations**, but many payers who operate multiple business lines may choose to implement these changes for their MA lines of business. CMS describes its proposal as "ground breaking"[2] 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 API (formerly known as, Payer-to-Payer Exchange); and
3. Provider Access API (including Bulk Data Provider Access API).

We break down each of the proposed API expansion requirements below. CMS is also proposing to adopt the Office of the National Coordinator for Health IT (ONC) API implementation specifications and implementation guides (IGs) for each of these APIs, and the Provider Directory API, in order to support true interoperability across providers and plans. The proposed rule change would permit use of updated IG versions, if the updated IG does not disrupt an end user's ability to access the data through any of the specified APIs. Notably, CMS is proposing different IGs for sharing prior authorization data for these three APIs. CMS seeks comments from Impacted Payers on the pros and cons of the required IGs, and specifically on whether US Core IG or PDex IG is the best IG for clinical data.

1. Patient Access API Data Expansion (starting January 1, 2023)

The Interoperability Final Rule requires Covered Payers (including MA organizations) to make the following types of data accessible through the Patient Access API:

- Claims data;
- Encounter data;
- Clinical data as represented in the U.S. Core Data for Interoperability, version 1 (USCDI v.1), if maintained in the member's record; and
- In some instances, formulary data.

Starting January 1, 2023, the Expanded Interoperability Proposed Rule would require Impacted Payers (which does not include MA organizations) to also make accessible pending and active prior authorizations, including the related clinical documentation and forms, within 1 business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization. The prior authorization data must include the date the prior authorization was approved, the date it ends, as well as the units and services approved and those used to date.

CMS describes "active" authorizations as "authorizations that are currently open and being used to facilitate current care and are not expired or no longer valid," and "pending" authorizations as "prior authorizations that are under review, either pending submission of documentation from the provider, or being evaluated by the payer's medical review staff, or for another reason have not yet had a determination made."[3]

Additionally, CMS proposes to **require** Impacted Payers to employ an attestation process for apps to attest to certain privacy policy practices prior to accessing data. Such a process is currently optional under the Interoperability Final Rule. Under the proposed rule, Impacted Payers must request that an app developer attest that:

- The app has a privacy policy that is publicly available and accessible at all times, including updated versions;
- The privacy policy is written in plain language;
- The app has "affirmatively shared" the privacy policy with the member prior to the member authorizing the app to access their health information; that is, the member had to take action to demonstrate they saw the privacy policy, such as click or check a box or boxes; and
- The privacy policy includes all of the following: How member information may be accessed, exchanged, or used, including whether it may be sold; Express member consent to the access, exchange or use, including express consent before information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction); If an app will access any other information from a member's device; and How to discontinue app access and what the app's policy and process is for disposing of member's data.

CMS proposes to require Impacted Payers—either independently or with the help of a vendor—to collect the attestations at the time the third-party app engages the API. The Impacted Payers must then notify the App user within 24 hours of requesting the attestation from the app of the status of the attestation—positive, negative, or no response, with a clear explanation of what each means. If the member does not respond to the notice in 24 hours, the Impacted Payer must give the app access. Impacted Payers must not discriminate between apps when

implementing this process. It must be applied equitably across all apps requesting access. Impacted Payers must also update their member education documents to include information about this attestation and notice process. Finally, the Expanded Interoperability Proposed Rule would require Impacted Payers to report quarterly to CMS metrics about patient use of the Patient Access API. The proposed reporting requirements include:

- Total number of unique beneficiaries whose data are transferred; and
- The number of unique members whose data are transferred more than once.

2. Payer-to-Payer API (starting January 1, 2023)

Starting on January 1, 2022, the Interoperability Final Rule requires a Covered Payer (but excluding state Medicaid and CHIP FFS programs), at a member's request, to exchange clinical data it maintains in the member's record with another payer (the "Payer-to-Payer Exchange"). A Covered Payer that receives such clinical data through a Payer-to-Payer Exchange must maintain that clinical data. While CMS encouraged the use of a FHIR-based API for this data exchange, it did not require it in the Interoperability Final Rule.

The Expanded Interoperability Proposed Rule would require exchange via FHIR-API and conformant with specific IGs for Impacted Payers; hence the name change to "Payer-to-Payer API." CMS further proposes to require use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification to support exchange for groups of members. Additionally, CMS proposes to expand the scope of Payer-to-Payer Exchange starting on January 1, 2023 by:

- Requiring that state Medicaid and CHIP FFS programs comply with the Payer-to-Payer API requirements;

- Requiring that claims and encounter data (but not remittances and member cost-sharing information), and pending and active prior authorization decisions, be made accessible via Payer-to-Payer API; and

- Requiring that Impacted Payers automatically share this data with a new payer or when a patient identifies concurrent coverage with another payer, at the end of the annual open enrollment period or, if they do not have such a period, the end of the first calendar quarter of each year, if the patient opts in to the data sharing. The receiving Impacted Payer must make the request for data within 1 week of the end of the enrollment period or first calendar quarter, and the disclosing Impacted Payer must respond within 1 business day of the request. This is in addition to the existing patient directed data sharing required by the Interoperability Final Rule. CMS further proposes to require Impacted Payers that provide concurrent coverage to a member share data quarterly if the patient opts in to the quarterly data sharing.

CMS proposes to exclude Non-Emergency Medical Transportation (NEMT), Prepaid Ambulatory Health Plans (PAHP) from the expanded Payer-to-Payer API requirements.

Impacted Payers (excluding NEMT PAHPs) who receive the enhanced 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 Payer-to-Payer API (in the form/format it was received). Impacted Payers would be required to receive up to 5 years of this historical data, and also to send such historical data via the Payer-to-Payer API for current members and former members up to 5 years after disenrollment. However, CMS is not proposing to require receiving payers to specifically review or act on the data. As CMS explained in the preamble to the 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).

But even if it is not required, CMS encourages Impacted Payers to at least consider previous payers' prior authorization decisions, and is seeking comment on whether payers should be prohibited from requiring patients to undergo repeat evaluations to reaffirm prior decisions without first reviewing the medical records and notes of the previous payer to determine if and why a repeat test is needed.

Finally, CMS is proposing to allow state Medicaid and CHIP FFS programs to seek an extension or exemption, and QHP Issuers on the FFEs to seek an exception, from the Payer-to-Payer API requirements under the same conditions as for the Provider Access API described below. As described below, CMS is requesting comment from Medicaid managed care plans as to whether similar extension criteria should be extended to them.

3. Provider Access API, including Bulk Data Provider Access API (starting January 1, 2023)

The Interoperability Final Rule rejected a proposal that would require Covered Plans to participate in trusted health information exchanges that would permit access by health care providers. But in the Expanded Interoperability Proposed Rule CMS is reversing course and going several steps farther for Impacted Payers (but excluding NEMT PAHPs).

CMS proposes to require that Impacted Payers build and maintain a Provider Access API for payer-to-provider data sharing of the same data in the Patient Access API (but excluding remittances and member cost-sharing information) for both individual patient requests and groups of patients. The same look back period 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. The Provider Access API would thus allow providers—without patient involvement and regardless of the provider's in- or out-of-network participation—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.

However, CMS is proposing to permit (but not require) Impacted Payers to implement a process to allow patients to **opt in** to the Provider Access API. CMS seek comments on this opt in option, whether CMS should instead finalize an **opt out** process, and in either case (opt in or opt out) if CMS should make it voluntary or required.

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. 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 emphasizes throughout the Expanded Interoperability Proposed Rule and the Interoperability Final Rule that it remains the payer's responsibility to ensure that data is shared in accordance with these existing privacy and security laws, including verifying the identity and authority of the provider requesting access. To this end, CMS would require Impacted Payers to have a process for generating each provider's current beneficiary roster. CMS is also seeking comment on whether CMS should further prescribe processes for verifying provider identity and authority, such as requiring treatment relationship attestations.

Similar to the Patient Access API member education requirements in the Interoperability Final Rule, CMS is proposing to require that Impacted Plans make educational resources available to providers that describe how a provider can request patient data using the payer's Provider Access API in nontechnical, simple, and easy-to-understand language. This education must be made available on the payer's website and through other appropriate mechanisms through which the payer ordinarily communicates with providers.

The Provider Access API must also use FHIR technology under the Expanded Interoperability Proposed Rule. CMS is further proposing to require use of Flat FHIR to support exchange for groups of patients. CMS refers to the Flat FHIR requirement as the "Bulk Data Provider Access API" and seeks comment on whether this is feasible and how best to implement this requirement given CMS's proposal that Impacted Payers maintain multiple different FHIR APIs based on single requests (*e.g.*, Patient Access API) and batch requests (*e.g.*, Payer-to-Payer API and Provider Access API).

Finally, CMS proposes to give state Medicaid or CHIP FFS agencies a mechanism by which to seek either a:

- 1-time **extension** for up to 1 year from the compliance deadline due to resource challenges (like funding); or

- 1 year **exemption** (per calendar year) from these proposed requirements if 90% of the covered items and services provided by the agency are through Medicaid or CHIP managed care contracts, or 90% of Medicaid/CHIP beneficiaries are enrolled with Medicaid or CHIP managed care organizations.

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 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.

CMS is not offering an extension (or exemption) to Medicaid managed care plans based on the belief that this work will benefit other business lines operated by a parent company of the managed care plans and thus by operation of this benefit will not impose an undue burden or unachievable goal on these plans. Medicaid managed care organizations should consider commenting on this belief, and educate CMS on the significant complexity and resources that will be necessary to implement a Provider Access API. CMS specifically requests comment on extension criteria, such as enrollment size, plan type, or some unique characteristic of certain plans that could hinder their achievement of the proposed requirements by the proposed compliance date. Impacted Payers should further consider requesting that CMS expressly provide that Impacted Payers may satisfy the Provider Access API requirements by participating in community health information exchange (HIE), regardless of the HIE's FHIR API capabilities.

CHANGES TO PRIOR AUTHORIZATION REQUIREMENTS

CMS also proposes to make changes to prior authorization requirements, including requiring payers to build separate FHIR APIs to allow providers to know in advance what documentation is needed for prior authorizations and to allow providers to send prior authorization requests and receive responses electronically, thereby eliminating the need for phone calls and faxes. Provider use of these FHIR APIs will be voluntary. The goal is to reduce provider burnout, redirect limited provider resources away from administrative process toward clinical care, and to reduce patient cost, burden and harm (such as when a patient abandons treatment altogether when authorization is delayed). **The proposed prior authorization changes will not apply to prescription drugs and/or covered outpatient drugs**.

Specifically, CMS proposes to require the following:

- **Document Requirement Lookup Service (DRLS) API (starting January 1, 2023):** Impacted Payers must build and maintain a FHIR-enabled DRLS API—that could be integrated with a provider's electronic health record (EHR)—to allow providers to electronically locate prior authorization requirements. CMS expects the DRLS API to work as follows: Providers will inquiry the DRLS API to determine if a prior authorization and documentation is required. If the response is yes, the DLRS API would indicate what is required, and might provide a link to submit the required documentation. In some cases, certain patient data available in the provider's system could be used to meet documentation requirements. CMS seeks comment on whether DRLS API should be rolled out in a phased approach and what interim solutions to accessing payer requirements for prior authorization may be appropriate, such as requiring posting of these requirements on payer websites. CMS is also proposing extensions, exemptions and exceptions for Medicaid and CHIP FFS program and QHP Issuers on the FFEs under the same conditions as those for Provider Access API and Payer-to-Payer API.

- **Prior Authorization Support (PAS) API (starting January 1, 2023):** Impacted Payers must build and maintain a FHIR-enabled electronic PAS API that has the capability to send provider prior authorization requests (including relevant forms or medical record documentation) and receive responses electronically within a provider's existing workflow and in compliance with HIPAA transaction standards. CMS offers this explanation of the workflow:

  > *"When a patient needs authorization for a service, the payer's PAS API would enable the provider, at the point of service, to send a request for an authorization. The API would send the request through an intermediary (such as a clearinghouse) that would convert it to a HIPAA compliant X12 278 request transaction for submission to the payer. It is also possible that the payer converts the request to a HIPAA compliant X12 278 transaction, and thus the payer acts as the intermediary. The payer would receive and process the request and include necessary information to send the response back to the provider through its intermediary, where the response would be transformed into a HIPAA compliant 278 response transaction. The response through the API would indicate whether the payer approves (and for how long), denies, or requests more information related to the prior authorization request, along with a reason for denial in the case of a denial."*[4]

  CMS is also proposing extensions, exemptions and exceptions for Medicaid and CHIP FFS program and QHP Issuers on the FFEs under the same conditions as those for DRLS API, Provider Access API and Payer-to-Payer API.

- **Denial Reason (starting January 1, 2023):** Impacted Payers must transmit through the proposed PAS API information regarding whether the payer approves (and for how long), denies, or requests more information related to the prior authorization request. With respect to denials of prior authorization requests, Impacted Payers must include the specific reason for a denial (such as missing documentation, medical necessity, exceeded limits, *etc.*), regardless of whether of the PAS 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.

  CMS is also soliciting comment on a future policy to prohibit post-service claim denials for items and services approved under a prior authorization, including any unintended consequences of such a policy and cost implications.

- **Shorter Prior Authorization Timeframes (starting January 1, 2023):** Impacted Payers (but not including QHP issuers on the FFEs) must send prior authorization decisions within 72 hours for urgent requests and a maximum 7 calendar days for standard requests (or fewer if state law establishes a shorter timeframe). For Medicaid managed care plans, CMS is proposing to continue to allow for a 14-day extension if the member requests it or the plan determines additional information is needed. CMS is not proposing to change the current regulatory consequences for payer failure to meet required timeframes, but solicits comments on whether CMS should adopt a policy whereby if a payer missed the required timeframe the prior authorization would be automatically approved. CMS also seeks comments on whether the exclusion of QHP issuers on the FFEs from this change would be operationally feasible or if it would have the unintended effect of increasing burden.

  Prior Authorization Metrics (starting March 31, 2023): Impacted Payers must publicly report annually data about the prior authorization process on their websites, such as the percent of prior authorization requests approved, denied, and ultimately approved after appeal, 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 whether some payers' practices of "gold carding"—relaxing or reducing prior authorization requirements for providers that have demonstrated a consistent pattern of compliance—should be included as a factor in quality star ratings for QHP Issuers.

ADDITIONAL REQUESTS FOR COMMENT AND REQUESTS FOR INFORMATION

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

- **Alternative Programs for Long-Term Authorizations for Terminal or Chronic Conditions.** CMS seeks input on whether there should be restrictions regarding requirements for repeat prior

authorizations for items and services for chronic conditions, or whether there can be approvals for long term authorizations.

- **Allowing Prior Authorizations to Follow the Patient**. CMS would like comment on whether a prior authorization decision should follow a patient when they change from one Impacted Payer plan to another, as well as whether prior authorizations should be valid and accepted for a specified amount of time.

- **Methods for Enabling Patients and Providers to Control Sharing of Health Information.** CMS would like comment on whether CMS should grant granular consent sharing by patients and providers; that is, what health information should be shared with whom and when. CMS is also seeking feedback on the ability to segment sensitive data—such as data protected by 42 CFR Part 2 (the federal Confidentiality of Substance Use Disorder Treatment Records regulations).

- **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 lag behind in EHR adoption and might not used an ONC certified EHR.

- **Reducing Burden and Improving Electronic Information Exchange of Documentation and Prior Authorization.** CMS would like input on advances in technology for prior authorization transactions that might support its interoperability goals, such as the benefits of certain implementation specifications and guides. CMS specifically requests comment on including an Improvement Activity under the Merit-based Incentive Payment System (MIPS) to support the use of PAS API by providers. CMS also seeks comment on the standardization of prior authorization forms.

- **Reducing the Use of Fax Machines for Health Care Data Exchange.** CMS seeks comment on how CMS can further reduce the use of facsimile (fax) technology across programs.

- **Accelerating the Adoption of Standards Related to Social Determinants of Health (SDOH) Data.** CMS would like feedback on what barriers exists to exchanging and using SDOH data (*e.g.*, housing instability, food insecurity).

WANT TO LEARN MORE?

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

- CMS Expanded Interoperability Proposed Rule
- CMS Interoperability and Patient Access Final Rule
- CMS Interoperability and Patient Access Proposed Rule

- CMS Public Listening Call: Improving Prior Authorization Processes and Promoting Patients' Electronic Access to Health Information Proposed Rule Listening Session
- CMS Fact Sheet: Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information CMS-9123-P
- CMS Blog: Reducing Provider and Patient Burden, and Promoting Patients' Electronic Access to Health Information
- CMS Interoperability and Patient Access final rule webpage
- CMS Interoperability and Patient Access Final Rule Call

ABOUT COPPERSMITH BROCKELMAN AND THE AUTHOR

Coppersmith Brockelman is working with health plans and 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 C.F.R. 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 and patient access laws (such as HIPAA, 42 C.F.R. Part 2, the ONC Information Blocking Rule, the CMS Interoperability and Patient Access Rule, and state laws), compliance with opioid treatment laws and regulations, health information exchange (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.

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] Seema Verma, CMS BLOG: REDUCING PROVIDER AND PATIENT BURDEN, AND PROMOTING PATIENTS' ELECTRONIC ACCESS TO HEALTH INFORMATION (Dec. 10, 2020) [hereinafter, CMS Blog].
[2] CMS Blog, *supra*.
[3] CMS, NOTICE OF PROPOSED RULE MAKING: 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 (RIN 0938-AT99), at 24-25 (unpublished release, Dec. 10, 2020) [hereinafter, Expanded Interoperability Proposed Rule].
[4] Expanded Interoperability Proposed Rule, at 91-92, *supra*.