All-State Medicaid and CHIP Call
December 17, 2024

Agenda

- Verbal Updates on the Clinic Regulations Finalized as Part of the CY 2025 OPPS Final Rule and HHS Extension of the COVID-19 PREP Act
- Overview of Medicaid and CHIP Interoperability Requirements
- Open Mic Q and A

Brief Verbal Update: Clinic Regulations Finalized as Part of the CY 2025 OPPS Final Rule

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Brief Verbal Update: HHS Extension of the COVID-19 PREP Act

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Overview of the Medicaid and CHIP Interoperability Requirements

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Interoperability and Patient Access Final Rule
Publication Date: May 2020

Background: Interoperability and Patient Access Final Rule (Released May 2020)

- **CMS Interoperability and Prior Authorization Final Rule (February 2024) builds on the technological foundation set in the May 2020 Interoperability and Patient Access Final Rule (CMS-9115-F)**
- **Patient Access Application Programming Interfaces (API):**
  - **Impacted Payers**: Medicaid and CHIP Fee-for-Service (FFS) programs, Medicaid managed care plans and CHIP managed care entities
  - **Compliance Requirement**: Implement and maintain an API allowing patients to access their **claims and encounter information**, and a defined sub-set of their **clinical information**.
- **Provider Directory API**:
  - **Impacted Payers**: Medicaid and CHIP Fee-for-Service (FFS) programs, Medicaid managed care plans and CHIP managed care entities
  - **Compliance Requirement:** Make provider directory information publicly available via an API, allowing third-party application developers to create services that help patients find providers for care and treatment, as well as help clinicians find other providers for care coordination.
- **Payer-to-Payer Data Exchange:**
  - **Impacted Payers**: Medicaid managed care plans and CHIP managed care entities
  - **Compliance Requirement**: Required to exchange certain clinical data at the patient's request, allowing the patient to take their cumulative health records with them as they change payers over time.

Advancing Interoperability and Improving Prior Authorization Processes Final Rule (CMS-0057-F)

Publication Date: February 2024

Definitions

- **Application Programming Interfaces (API)** - 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.
- **Prior Authorization (PA)** - Refers to the process through which clinicians, hospitals, clinics, and other providers obtain approval from Medicaid or CHIP payers before providing care. PA is made up of two parts - a “request” from a provider, and a “decision” by a payer. We refer to the provider’s workflow and associated information and documentation as the “prior authorization request” and the payer’s processes and associated information and documentation as the “prior authorization decision.”
- **Items and Services** – The term “items and services” is used when discussing PA APIs and process improvements. Because the processes and standards for PA of drugs differ from the other “items and services,” the term and related policies do not apply to drugs of any type.
- **Medicaid and CHIP Payers** – State Medicaid and CHIP Agencies operating FFS programs, Medicaid Managed Care Plans and CHIP Managed Care Entities.
- **Fast Healthcare Interoperability Resources (FHIR)** – APIs described in this deck must conform with FHIR standards.

CMS Advancing Interoperability and Improving Prior Authorization Processes Final Rule

- On February 8, 2024, CMS published the *Advancing Interoperability and Improving Prior Authorization Processes* final rule (CMS-0057-F) to further drive interoperability, empower patients, and improve prior authorization processes through policies and technology.
- This final rule builds upon existing policies by outlining requirements for additional information that certain payers must provide via the existing Patient Access API and new requirements for certain payers to develop three additional APIs:
  - **Provider Access API -** Enables the exchange of patient information between a patient's payers and in-network providers.
  - **Payer-to-Payer API -** Enables the exchange of patient information between a patient's new and previous payers, and between concurrent payers.
  - **Prior Authorization API -** Enables providers to locate documentation and prior authorization requirements directly from their electronic health record (EHR) or practice management system and the exchange of prior authorization requests and decisions.

Patient Access API

- Building off the May 2020 Interoperability and Patient Access Final Rule, states and Medicaid and CHIP managed care plans will need to enhance API technologies to expand the types of health informational content accessible to beneficiaries and enrollees via the existing Patient Access API to inform better patient decision making.
- **API Data Requirements**: Medicaid and CHIP payers will be required to add information about prior authorizations (excluding those for drugs) to the data available via the Patient Access API. In addition to giving patients access to more of their data, this will help patients understand their payer's prior authorization process and its impact on their care.
- **API Usage Metrics**: To assess Patient Access API usage, beginning January 2026, Medicaid and CHIP payers are required to report annual metrics to CMS about Patient Access API usage.
- **Effective Date:** January 1, 2027 for Medicaid and CHIP FFS & by the rating period beginning on or after January 1, 2027 for Medicaid and CHIP managed care.

Provider Access API

- **API Requirements :** Medicaid and CHIP payers must implement and maintain a Provider Access API to share patient data with providers with whom the patient has a treatment relationship.
- **Data Requirements:** The API must make available, in a content standard adopted by Office of the National Coordinator (ONC), individual claims and encounter data (excluding provider remittances and enrollee cost-sharing information), and specified prior authorization information (excluding those for drugs).
- **Attribution:** Medicaid and CHIP payers are required to develop and maintain an attribution process to associate beneficiaries with their providers to ensure that the payer only sends data when a treatment relationship is verified.
- **Opt Out:** Medicaid and CHIP agencies are required to maintain a process for patients to opt out of having their information available and shared via the Provider Access API.
    - The opportunity to opt out must be provided before the beneficiary's information is made available in the Provider Access API, and at any time while the beneficiary is enrolled in Medicaid or CHIP.
- **Effective Date:** January 1, 2027 for Medicaid and CHIP FFS & by the rating period beginning on or after January 1, 2027 for Medicaid and CHIP managed care.

Payer-to-Payer API

- **This Payer-to-Payer API replaces the Payer-to-Payer data exchange policy included in the May 2020 Interoperability and Patient Access Final Rule**
- **API Requirements:** Medicaid and CHIP payers must implement and maintain a Payer-to-Payer API to support care continuity when a beneficiary changes (or has concurrent) payers and ensure that records follow the beneficiary to ensure continued access to data in their medical records.
- **Data Requirements**: The API will make available claims and encounter data (excluding provider remittances and enrollee cost-sharing information), all data classes and data elements in a content standard adopted by ONC, and information about prior authorizations (excluding those for drugs and those that were denied). Medicaid and CHIP payers are only required to share patient data with a date of service within five years of the request for data.
- **Opt In:** Medicaid and CHIP agencies must establish and maintain a process to gather permission from beneficiaries to exchange their information via the Payer-to-Payer API.
  - The opportunity to opt in must be offered no later than 1 week after enrollment and beneficiaries must be allowed to change their decision at any time.
  - This requirement does not apply to data exchanges between a state Medicaid or CHIP program and its contracted managed care plans or entities.
- **Effective Date:** January 1, 2027 for Medicaid and CHIP FFS & by the rating period beginning on or after January 1, 2027 for Medicaid and CHIP managed care.

Beneficiary Control of Data Sharing: Educational Resources & Operational Considerations

- Medicaid and CHIP agencies must provide beneficiaries with plain-language educational resources that explain the benefits of data sharing via the Provider Access API and Payer-to-Payer API, the beneficiary's ability to opt in/out, and instructions for doing so.
- States have flexibility in how they implement their processes to gather beneficiary data exchange permissions.
  - An individual's opt out/in preference could be requested on the application for Medicaid or CHIP, or through a beneficiary portal on a mobile application or website.
  - States should make available alternatives methods such as mail, fax, or telephone for beneficiaries with limited access to internet and for those who do not want to submit their preference via an electronic portal.

Prior Authorization API

- **API Requirement:** Medicaid and CHIP payers must implement and maintain a Prior Authorization API.
- **Identifying Prior Authorization Requirements:** The API must be populated with the list of items and services (excluding drugs) that require prior authorization from the payer. The API must also identify the payer's documentation requirements for all items and services (excluding drugs) that require prior authorization.
- **Exchanging Prior Authorization Requests and Responses:** The API must support the creation and exchange of prior authorization requests from providers and responses from payers.
- **Decision Timeframes:** In addition to API requirements to improve PA processes, the final rule also revised and established PA decision timeframes for Medicaid and CHIP managed care and FFS payers, respectively.
- **Effective Date:** January 1, 2027 for Medicaid and CHIP FFS & by the rating period beginning on or after January 1, 2027 for Medicaid and CHIP managed care.

Existing Regulations: Prior Authorization Decision Timeframes

- **Medicaid and CHIP Managed Care:**
  - For standard authorization decisions, provide notice as expeditiously as the enrollee's condition requires and within state established time frames that may not exceed 14 calendar days after receiving the request for service.
  - For expedited authorization decisions, provide notice as expeditiously as the enrollee's condition requires and no later than 72 hours after receipt of the request for service.
  - Standard and expedited authorization decisions may have an extension of up to 14 additional calendar days in certain situations.
- **CHIP FFS:**
  - In accordance with the medical needs of the patient, within 14 days after receipt of a request for services. A possible extension of up to 14 days may be permitted if the enrollee requests the extension or if the physician or health plan determines that additional information is needed; or
  - In accordance with existing state law regarding prior authorization of health services.
- **Medicaid FFS:** No existing regulations on decision timeframes.

New Prior Authorization Requirements Established in the Final Rule

- **Prior Authorization Decision Timeframes**: All Medicaid and CHIP payers must send notice of prior authorization decisions as expeditiously as the beneficiary's condition requires, and within:
  - **72 hours** for expedited requests (unless a shorter minimum timeframe is established under applicable state law); and
  - **Seven (7) calendar days** for standard requests (unless a shorter minimum timeframe is established by the state (e.g., administrative law or managed care contract).
  - In some cases, authorization determinations may be extended up to 14 calendar days (after receiving the request).
- **Provider Notice (with Denial Reason):**
  - Per 42 CFR 431.80(a) and 438.242(b)(8) Medicaid and CHIP payers must provide a specific reason for denied PA decisions (excluding drugs), regardless of the method used to send the prior authorization request.
  - Reasons may be communicated via portal (may include existing payer messaging portal), fax, email, mail, or phone.
- **Prior Authorization Annual Metrics**: Medicaid and CHIP payers must publicly report certain prior authorization metrics annually by posting them on their website.
- **Effective Date:** January 1, 2026 for Medicaid and CHIP FFS & by the rating period beginning on or after January 1, 2026 for Medicaid and CHIP managed care.

Beneficiary Notice and Fair Hearing/Review Rights: FFS

- Medicaid and CHIP have longstanding beneficiary notice and fair hearing/review rights regulations which have and will continue to apply to FFS Medicaid and CHIP prior authorization requests, independent of APIs.
- **Beneficiary notices:**
  - States must provide the beneficiary with timely and adequate written notice of any decision regarding the beneficiary's prior authorization request.
  - For Medicaid, this notice must include the content described at 42 CFR 435.917 and at 42 CFR part 431, subpart E, including information about the beneficiary's right to request a fair hearing. States must provide the beneficiary at least a 10-day advance written notice of any termination of, suspension of, or reduction in a current prior authorization, including information about the right to request a fair hearing.
  - For CHIP, states must provide beneficiaries timely written notice of any determinations required to be subject to review under 42 CFR 457.1130 that includes the reasons for the determination, an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, and the way a review can be requested.
- **Beneficiary fair hearings/review rights:**
  - States must provide the beneficiary the opportunity to request a fair hearing or CHIP review if a prior authorization request is:
    - Denied in whole or in part
    - Not acted upon with reasonable promptness
    - Terminated, suspended, or reduced (current prior authorizations only)

Enrollee Notices and Appeals: Managed Care

- Medicaid and CHIP managed care have longstanding enrollee notice and appeals requirements which apply to prior authorization requests, independent of API requirements or usage.
- **Enrollee notices**
  - The MCO, PIHP, or PAHP must provide the enrollee with timely and adequate written notice of any adverse benefit determination.
  - This notice must include the content specified at 42 CFR 438.404, including the enrollee's right to appeal the adverse benefit determination as well as information about the right to request an external medical review (if available) and/or a state fair hearing.
  - The MCO, PIHP, or PAHP must generally provide the enrollee at least 10-days advance written notice of any termination, suspension, or reduction of previously authorized services, and include information about the enrollee's right to appeal and the right to request an external medical review (if available) and/or a state fair hearing.
  - The MCO, PIHP, or PAHP must provide the enrollee the opportunity to request an appeal for:
    - The denial or limited authorization of a requested service.
    - Service authorization decisions not reached within the timeframes specified in 42 CFR 438.210(d).
    - The reduction, suspension, or termination of a previously authorized service.

Compliance Flexibilities: Extensions and Exemptions

Addressing Challenges for State Agencies Operating FFS Programs

- **Implementation Challenges:** We recognize that states may face challenges in meeting new API deadlines established by the 2024 final rule that are unique to their systems and processes, and that more time can be needed to properly plan for system upgrades and adaptations:
  - **Legislative Processes.** State payers may need time to engage legislatures on budget requests and resource needs to implement API systems requirements.
  - **State Procurement Processes**. Procedures to secure and onboard contractors can often be extensive and time-consuming and may result in implementation delays.
  - **State Staffing Processes.** Position creation, selection and onboarding of new state employee hires dedicated to supporting API systems efforts may result in delays.
  - **PHE Unwinding:** COVID-19 recovery efforts are an ongoing challenge that CMS acknowledges as having an impact on future IT work. As efforts continue, state operational resources remain over-extended.
  - **Other Operational Burden.** It may be improper and inefficient to require state Medicaid/CHIP agencies with small FFS populations to implement new API requirements.
- **Compliance Flexibilities:** As explained in the coming slides, CMS will work with states operating Medicaid or CHIP FFS programs on requests for extensions or exemptions due to specified operational challenges. Any extension or exemption flexibility granted will be limited and based on unique program circumstances.

Extension Criteria: FFS

- States can **request a one-time, one-year extension** from the API technology requirements as a part of their annual Advance Planning Document (APD) submission. **States must submit requests through the APD process by May 31, 2026**.
- The application request must be approved before the compliance date(s) of the requirement(s) from which the state is seeking an extension.
- The application must also include a **narrative justification** describing:
  - The specific reasons why the state cannot implement the requirement(s) by the compliance date and why those reasons result from circumstances that are unique to the agency operating the Medicaid or CHIP FFS program.
  - A report on completed and ongoing state activities that evidence a good faith effort towards compliance.
  - A comprehensive plan to meet the requirements no later than one year after the compliance date.
- **Applicability:** CMS will **consider extension requests** for Provider Access, Payer-to-Payer, and Prior Authorization API requirements**,** but **extensions cannot be granted** for the Patient Access API requirements.
- **Contact Information**: States should reach out to their **MES state officer** to discuss specific challenges.

Exemption Criteria: FFS

- States operating a Medicaid program or separate CHIP **in which 90 percent or more of beneficiaries are enrolled in Medicaid managed care organizations** (defined in § 438.2) **or CHIP managed care organizations** (defined in § 457.10), **may request an exemption** for its FFS program(s) from most new API policies.
- **Requests must be submitted by May 31, 2026 for the requirement(s) from which the state is seeking an exemption** and must be submitted in writing as part of a state's annual APD. The application should include:
  - Documentation that the state meets the exemption threshold based on enrollment data from the most recent CMS "Medicaid Managed Care Enrollment and Program Characteristics" (or successor) report for Medicaid or based on enrollment data from section 5 of the most recently accepted CHIP annual report submitted in the CHIP Annual Plan Template System (CARTS).
  - An alternative plan to ensure that API counterparties (e.g., providers, other payers) have efficient electronic access to the same information through other means while the exemption is in effect.
- If shifts in managed care enrollment cause a state to no longer meet the 90 percent threshold, CMS must be notified in writing and the state must obtain CMS approval of a timeline for API compliance within two (2) years of the exemption expiration date.
- **Contact Information**: States should reach out to their **MES state officer** for APD-submission process.

FFS Prior Authorization Decision Timeframes: Addressing extenuating circumstances

- We recognize the unique challenges some states expressed through public comments concerning the practical ability to implement the new prior authorization timeframes in state Medicaid and CHIP FFS programs by January 1, 2026. We understand that states often require longer timeframes to create new positions, adjust procurement arrangements, and rework system processes.
- We are willing to work with state Medicaid and CHIP FFS programs that may be unable to meet the new compliance date for the prior authorization timeframes.
- Any flexibility granted to a state Medicaid or CHIP FFS program for the implementation of the new prior authorization decision timeframe requirements will be temporary and limited to the unique circumstances of the program.
- **CMS Contact Information:** States should contact their Medicaid **state lead** or CHIP **project officer** before **April 1, 2025**, to discuss their extenuating circumstances.

Next Steps:

Advance Planning Document (APD) Submissions for Extension/Exemption Requests & FFP Opportunities for Implementation Activities

Exemption and Extension Request

- **State Medicaid and CHIP agencies should begin evaluating the API requirements and work needed to meet the new requirements.**
- If needed, states will submit exemption and extension requests for the applicable Provider Access, Payer-to-Payer, and Prior Authorization API requirements through the APD Process.
- Decisions on requests will be included as part of the APD Approval Letter.
  - Approvals will be posted on the CMS Website.
- Ask your **MES State Officer** if you have any questions about this process or which **APD document is most appropriate for an extension or exemption request.**
- As a reminder, states should direct any questions related to extension requests to meet the **newly established prior authorization timeframes** to their **Medicaid State Lead of CHIP Project Officer** before April 1, 2025, to discuss their extenuating circumstances.

Enhanced Federal Financial Participation (FFP) for System Development

- 90%, 75%, and 50% FFP may be available at each step of the System Development Lifecycle.*

*Refer to State Medicaid Manual (https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021927) and State Medicaid Director Letter 16-004 (https://www.medicaid.gov/federal-policy-guidance/downloads/smd16004.pdf) for more information on available enhanced FFP.

Questions?