| **Summary** |
| --- |
| This final rule will improve the electronic exchange of health care data and streamline processes related to prior authorization through new requirements for Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state Children’s Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally facilitated Exchanges (FFEs). This final rule will also add new measures for eligible hospitals and critical access hospitals (CAHs) to report under the Medicare Promoting Interoperability Program and for MIPS eligible clinicians to report under the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS). These policies, taken together, will reduce overall payer and provider burden and improve patient access to health information while continuing CMS’s drive toward interoperability in the health care market.[[1]](#footnote-2)  The CMS Interoperability and Prior Authorization Final Rule (CMS–0057–F) expands on the [CMS Interoperability and Patient Access Final Rule (CMS-9115-F)](https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-patient-access-final-rule-cms-9115-f) released May 1, 2020, which was intended to move the health care ecosystem in the direction of interoperability, and to signal our commitment to the vision set out in the 21st Century Cures Act and [Executive Order 13813](https://www.federalregister.gov/executive-order/13813) to improve quality and accessibility of information that Americans need to make informed health care decisions, including data about health care prices and outcomes, while minimizing reporting burdens on affected health care providers and payers.  **Effective Date for the CMS Interoperability and Prior Authorization Final Rule: April 8, 2024, unless implementation dates are otherwise specified within the rule.** |

**Patient Access API Final Policies and Cross References**

**(Table B1—Page 8783)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Requirement** | **Medicare Advantage** | **Medicaid FFS** | **Medicaid Managed Care** | **CHIP FFS** | **CHIP Managed Care** |
| Adding prior authorization information (compliance date—January 1, 2027) | 42 CFR 422.119(b)(1)(iv)(A) | 42 CFR 431.60(b)(5)(i) | Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5) | 42 CFR 457.730(b)(5)(i) | Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d) |
| Timeframe for prior authorization information availability (compliance date—January 1, 2027) | 42 CFR 422.119(b)(1)(iv)(B) | 42 CFR 431.60(b)(5)(ii) | Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5) | 42 CFR 457.730(b)(5)(ii) |
| Reporting Patient Access API metrics (compliance date—January 1, 2026) | 42 CFR 422.119(f) | 42 CFR 431.60(f) | Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5)(iii) | 42 CFR 457.730(f) |
| Revisions to the scope of clinical data to be made available via the Patient Access API (effective date of the final rule). | 422.119(b)(1)(iii) | 42 CFR 431.60(b)(3) | Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5) | 42 CFR 457.730(b)(3) |
| Patient Access API denial/discontinuation of access (effective date of the final rule). | 422.119(e)(2) | 42 CFR 431.60(e)(2) | Through cross reference to 42 CFR 431.60 at 42 CFR 438.242(b)(5) | 42 CFR 457.730(e)(2) |

**Provider Access API Final Policies and Cross References**

**(Table C1—Page 8816)**

| **Requirement** | **Medicare Advantage** | **Medicaid FFS** | **Medicaid Managed Care** | **CHIP FFS** | **CHIP Managed Care** |
| --- | --- | --- | --- | --- | --- |
| Provider Access API for individual patient information (compliance date January 1, 2027) | 42 CFR 422.121(a)(1) | 42 CFR 431.61(a)(1) | Through cross reference to 42 CFR 431.61 at 42 CFR 438.242(b)(7) | 42 CFR 457.731.(a)(1) | Through cross reference to 42 CFR 438.242 at 42 CFR 457.12.33(d) |
| Data content (compliance date January 1, 2027) | 42 CFR 422.121(a)(2) | 42 CFR 431.61(a)(2) | Through cross reference to 42 CFR 431.61 at 42 CFR 438.242(b)(7) | 42 CFR 457.731.(a)(2) |
| Applicability of Provider Access API to NEMT PAHPS (compliance date January 1, 2027) | Not Applicable (NA) | NA | 42 CFR 438.9(b)(7) | NA | 42 CFR 457.1206(b)(/6) |
| Attribution (compliance date January 1, 2027) | 42 CFR 422.121(a)(3) | 42 CFR 431.61(a)(3) | Through cross reference to 42 CFR 431.61 at 42 CFR 438.242(b)(7) | 42 CFR 457.731(a)(3) | Through cross reference to 42 CFR 438.242 at 42 CFR 457.12.33(d) |
| Opt Out (compliance date January 1, 2027) | 42 CFR 422.121(a)(4)(i) | 42 CFR 431.61(a)(4)(i) | Through cross reference to 42 CFR 431.61 at 42 CFR 438.242(b)(7) | 42 CFR 457.731(a)(4)(i) |
| Patient educational resources regarding API (compliance date January 1, 2027) | 42 CFR 422.121(a)(4)(ii) | 42 CFR 431.61(a)(4)(ii) | Through cross reference to 42 CFR 431.61 at 42 CFR 438.242(b)(7) | 42 CFR 457.731(a)(4)(ii) |
| Provider educational resources regarding API (compliance date January 1, 2027) | 42 CFR 422.121(a)(5) | 42 CFR 431.61(a)(5) | Through cross reference to 42 CFR 431.61 at 42 CFR 438.242(b)(7) | 42 CFR 457.731(a)(5) |
| Extension for Medicaid and CHIP FFS (effective date of the final rule) | NA | 42 CFR 431.61(c)(1) | NA | 42 CFR 457.731(c)(1) | NA |
| Exemption for Medicaid and CHIP FFS (effective date of the final rule) | NA | 42 CFR 431.61(c)(2) | NA | 42 CFR 457.731(c)(2) | NA |

**Payer to Payer Data Exchange Final Policies and Cross References**

**(Table D1—Page 8853)**

| **Requirement** | **Medicare Advantage** | **Medicaid FFS** | **Medicaid Managed Care** | **CHIP FFS** | **CHIP Managed Care** |
| --- | --- | --- | --- | --- | --- |
| Technical standards (compliance date January 1, 2027) | 42 CFR 422.121(b)(1) | 42 CFR 431.61(b)(1) | Through cross reference to 42 CFR 431.61(b)(1) at 42 CFR 438.242(b)(7) | 42 CFR 457.731(b)(1) | Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d) |
| Opt in (compliance date January 1, 2027) | 42 CFR 422.121(b)(2) | 42 CFR 431.61(b)(2) | NA | 42 CFR 457.731(b)(2) | NA |
| Identify previous and concurrent payers (compliance date January 1, 2027) | 42 CFR 422.121(b)(3) | 42 CFR 431.61(b)(3) | NA | 42 CFR 457.731(b)(3) | NA |
| Data exchange requirement (compliance date January 1, 2027) | 42 CFR 422.121(b)(4) and (5) | 42 CFR 431.61(b)(4) and (5) | Through cross reference to 42 CFR 431.61(b)(4) and (5) at 42 CFR 438.242(b)(7) | 42 CFR 457.731(b)(4) and (5) | Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d) |
| Accessible content and API requirements (compliance date January 1, 2027) | 42 CFR 422.121(b)(4)(ii) | 42 CFR 431.61(b)(4)(ii) | Through cross reference to 42 CFR 431.61(b)(4)(ii) at 42 CFR 438.242(b)(7) | 42 CFR 457.731(b)(4)(ii) |
| Data Incorporation (compliance date January 1, 2027) | 42 CFR 422.121(b)(4)(v) | 42 CFR 431.61(b)(4)(v) | Through cross reference to 42 CFR 431.61(b)(4)(v) at 42 CFR 438.242(b)(7) | 42 CFR 457.731(b)(4)(v) |
| Concurrent coverage data exchange requirements (compliance date January 1, 2027) | 42 CFR 422.121(b)(6) | 42 CFR 431.61(b)(6) | Through cross reference to 42 CFR 431.61(b)(6) at 42 CFR 438.242(b)(7) | 42 CFR 457.731(b)(6) |
| Patient educational resources regarding API (compliance date January 1, 2027) | 42 CFR 422.121(b)(7) | 42 CFR 431.61(b)(7) | Through cross reference to 42 CFR 431.61(b)(7) at 42 CFR 438.242(b)(7) | 42 CFR 457.731(b)(7) | Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d) |
| Extension for Medicaid and CHIP FFS (effective date of the final rule | NA | 42 CFR 431.61(c)(1) | NA | 42 CFR 457.731(c)(1) | NA |
| Exemption for Medicaid and CHIP FFS (effective date of the final rule. | NA | 42 CFR 431.61(c)(2) | NA | 42 CFR 457.731(c)(2) | NA |

**Final Prior Authorization Decision Timeframes (Excluding Drugs) Beginning in 2026**

**(Table E1—Page 8883)**

| **Payer** | **Final Expedited Prior Authorization Decision Timeframes** | **Final Standard Prior Authorization Decision Timeframes** |
| --- | --- | --- |
| MA Organizations and Applicable Integrated Plans | As expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request.\*  42 CFR 422.572(a)  42 CFR 422.631(d)(2)(iv) | As expeditiously as the enrollee's condition requires but no later than 7 calendar days after receiving the request for the standard organization determination\* and standard integrated organization decision. |
| Medicaid Managed Care Plans | As expeditiously as the enrollee's health condition requires and no later than 72 hours after receipt of the request for service.  42 CFR 438.210(d)(2) | As expeditiously as the enrollee's condition requires and within state established timeframes that may not exceed 7 calendar days after receiving the request for service.  42 CFR 438.210(d)(l) |
| CHIP Managed Care Entities | As expeditiously as the enrollee's health condition requires but no later than 72 hours after receipt of the request for service unless a shorter minimum time frame is established under state law.  42 CFR 457.1230(d) | As expeditiously as the enrollee's condition requires but no later than 7 calendar days after receiving the request for service unless a shorter minimum time frame is established under state law.  42 CFR457.1230(d) |
| Medicaid FFS | As expeditiously as a beneficiary's health condition requires, but in no case later than 72 hours after receiving the request, unless a shorter minimum time frame is established under state law.  42 CFR440.230(e)(l)(ii) | As expeditiously as a beneficiary's health condition requires, but in no case later than 7 calendar days after receiving the request, unless a shorter minimum timeframe is established under state law.  42 CFR 440.230(e)(l)(i) |
| CHIP FFS | In accordance with the medical needs of the patient, but no later than 72 hours after receiving the request for an expedited determination.  42 CFR 457.495(d)(1) | In accordance with the medical needs of the patient, but no later than 7 calendar days after receiving the request for a standard determination.  42 CFR 457.495(d)(l) |

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

**New or Modified Prior Authorization Notification Requirements**

**(Table E2—Page 8888)**

| **Impacted Payer** | **Final** | **CFR Citation** |
| --- | --- | --- |
| MA Organizations | Notification Requirement to Enrollees | 42 CFR 422.568(b)(I) |
| Applicable Integrated Plans | Notification Requirement to Enrollees—Standard Decision | 42 CFR 422.631(d)(2)(i)(B) |
| Applicable Integrated Plans | Notification Requirement to Enrollees—Expedited Decision | 42 CFR 422.631(d)(2)(iv) |
| Medicaid FFS | Notice to Providers of Decisions on Expedited and Standard Prior Authorization Requests | 42 CFR 440.230(e)(l) |
| Medicaid Managed Care Plans | Standard Prior Authorization Decision Notification | 42 CFR 438.210(d)(l)(i) |
| Medicaid Managed Care Plans | Expedited Prior Authorization Decision Notification | 42 CFR 438.210(d)(2)(i) |
| CHIP Managed Care Entities | Prior Authorization Decisions | Through cross reference to 42  CFR438.210 at42 CFR 457.1230 d |
| CHIP FFS | Prior Authorization Decisions | 42 CFR 457.495(d)(l) |

**Improving Prior Authorization Processes Final Policies**

**(Table E4—Page 8895)**

| **Requirement** | **Medicare Advantage** | **Medicaid FFS** | **Medicaid Managed Care** | **CHIP FFS** | **CHIP Managed Care** |
| --- | --- | --- | --- | --- | --- |
| Prior Authorization API (compliance date January 1, 2027) | 42 CFR 422.122(b) | 42 CFR 431.80(b) | Through cross reference to 42 CFR 431.80(b) at 42 CFR 438.242 (b)(7) | 42 CFR 457.732(b) | Through existing cross reference to 42 CFR 438.242 at 42 CFR 457.1233(d) |
| Information about the status of prior authorization (compliance date January 1, 2027) | 42 CFR 422.122(b)(4) | 42 CFR 431.80(b)(4) | Through cross reference to 42 CFR 431.80(b) at 42 CFR 438.242 (b)(7) | 42 CFR 457.732(b)(4) |
| Denial reason for prior authorization (compliance date January 1, 2026) | 42 CFR 422.122(a) | 42 CFR 431.80(a) | Through cross reference to 42 CFR 431.80(a) at 42 CFR 438.242 (b)(8) | 42 CFR 457.732(a) |
| Standard prior authorization timeframe (compliance date January 1, 2026) | 42 CFR 422.568(b)(1) | 42 CFR 440.230(e)(1)(i) | 42 CFR 210(d)(1) | 42 CFR 457.495(d)(1) | Through existing cross reference to 42 CFR 438.210 at 42 CFR 457.1230(d) |
| Expedited prior authorization timeframe (compliance date January 1, 2026) | No change to existing rules on the timing. | 42 CFR 440.230(e)(1)(ii) | 42 CFR 210(d)(2) | 42 CFR 457.495(d)(1) | NA |
| Extension for state Medicaid and CHIP FFS (effective date of the final rule) | NA | 42 CFR 431.80(c)(1) | NA | 42 CFR 457.732(d)(1) | NA |
| Exemption for state Medicaid and CHIP FFS (effective date of the final rule) | NA | 42 CFR 431.80(c)(2) | NA | 42 CFR 457.732(d)(2) | NA |
| Public reporting for prior authorization metrics (compliance date March 31, 2026) | 42 CFR 422.122(c) | 42 CFR 440.230(e)(3) | 42 CFR 438.210(f) | NA | Through cross reference to 42 CFR 438.210 at 42 CFR 457.1230(d) |
| Prior authorization metrics (compliance date March 31, 2026) | 42 CFR 422.122(c) | NA | NA |

**Impacted Payers Eligible to Apply for Extensions, Exemptions, or Exceptions by Application Programming Interface**

**in the CMS Interoperability and Prior Authorization Final Rule**

**(Table F1—Page 8907)**

|  |  |  |
| --- | --- | --- |
| **API** | **Eligible for Extension** | **Eligible for Exemption** |
| Provider Access API | * Medicaid FFS program * CHIP FFS program | * Medicaid FFS program with ≥ 90% in MCOs * CHIP FFS program with ≥ 90% in MCOs * NEMT PAHP\* |
| Payer-to-Payer API | * Medicaid FFS program * CHIP FFS program | * Medicaid FFS program with ≥ 90% in MCOs * CHIP FFS program with ≥ 90% in MCOs |
| Prior Authorization API | * Medicaid FFS state program * CHIP FFS program | * Medicaid FFS program with ≥ 90% in MCOs * CHIP FFS state agency with ≥ 90% in MCOs |

\*NEMT PAHPs are not subject to the Provider Access and Payer-to-Payer API requirements and do not need to apply to CMS for this exemption.

**Required Standards and Recommended Implementation Guides to Support API Implementation**

**(Table H3—Page 8945)**

| **API** | ***Required* Standards** | ***Recommended* Implementation Guides** |
| --- | --- | --- |
| Patient Access API | 45 CFR 170.215(a)(l) HL7 FHlR Release 4.0.l  45 CFR l 70.215(b)(l)(i) HL7 FHIR US Core IG  STU 3.l.l.\*\*\*  45 CFR 170.215(c)(l) HL7 SMART Application Launch Framework IG Release 1.0.0.\*\*\*  45 CFR l 70.215(e)(l) Open ID Connect Core 1.0, incorporating errata set 1 | HL7 FHlR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: [CARIN Blue Button Implementation Guide (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/carin-bb/history.html)  HL7 FHIR Da Vinci Payer Data Exchange (PDex) TG STU 2.0.0. URL: [Da Vinci Payer Data Exchange (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/davinci-pdex/history.html)  HL7 FHIR Da Vinci - Payer Data Exchange (PDex) US Drug Formulary IG STU 2.0.1. URL: [US Drug Formulary (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/Davinci-drug-formulary/history.html) |
| Provider Access API | 45 CFR l 70.215(a)(l) HL7 FHlR Release 4.0.1  45 CFR 170.215(b)(l)(i) HL7 FHIR US Core JG STU 3.1.l.\*\*\*  45 CFR 170.215(c)(l) HL7 SMART Application Launch Framework TG Release 1.0.0.\*\*\*  45 CFR l 70.215(d)(l) FHIR Bulk Data Access (Flat FHIR) IG (vl.0.0: STU I) | HL7 FHlR CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: [CARIN Blue Button Implementation Guide (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/carin-bb/history.html)  HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG STU 2.0.0. URL: [Da Vinci Payer Data Exchange (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/davinci-pdex/history.html)  45 CFR 170.215(c)(2) HL7 SMART App Launch IG, Release 2.0.0 to support Backend Services Authorization. URL: [HL7.FHIR.UV.SMART-APP-LAUNCH\Backend Services - FHIR v4.0.1](https://hl7.org/fhir/smart-app-launch/STU2/backend-services.html) |
| Provider Directory API | 45 CFR l 70.215(a)(l) HL7 FHlR Release 4.0.1  45 CFR l 70.215(b)(l)(i) HL7 FHlR US Core lG STU3.l.l.\*\*\* | HL7 FHlR Da Vinci Payer Data Exchange (PDex) Plan Net lG STU 1.1.0. URL: [DaVinci PDEX Plan Net (FHIR IG) (hl7.org)](https://www.hl7.org/fhir/us/davinci-pdex-plan-net/history.html) |
| Payer to Payer API | 45 CFR l 70.215(a)(l) HL7 FHIR Release 4.0.1  45 CFR l 70.215(b)(l)(i) HL7 FHIR US Core IG STU 3.1.l.\*\*\*  45 CFR l 70.215(d)(l) FHIR Bulk Data Access (Flat FHIR) lG (vl.0.0: STU 1) | HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) IG STU 2.0.0. URL: [CARIN Blue Button Implementation Guide (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/carin-bb/history.html)  HL7 FHTR Da Vinci Payer Data Exchange (PDex) TG STU 2.0.0. URL: [Da Vinci Payer Data Exchange (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/davinci-pdex/history.html)  45 CFR 170.215(c)(2) HL7 SMART App Launch IG, Release 2.0.0 to support Backend Services Authorization. URL: [HL7.FHIR.UV.SMART-APP-LAUNCH\Backend Services - FHIR v4.0.1](https://hl7.org/fhir/smart-app-launch/STU2/backend-services.html) |
| Prior Authorization API | 45 CFR 170.215(a)(l) HL7 FHTR Release 4.0.1  45 CFR 170.215(b)(l)(i) HL7 FHIR US Core JG STU 3.1.1.\*\*\*  45 CFR 170.215(c)(l) HL7 SMART Application Launch Framework TG Release 1.0.0.\*\*\* | HL7 FHTR Da Vinci - Coverage Requirements Discovery (CRD) TG STU 2.0.1. URL: [Da Vinci Coverage Requirements Discovery (CRD) FHIR IG (hl7.org)](https://hl7.org/fhir/us/davinci-crd/history.html)  HL7 FHTR Da Vinci - Documentation Templates and Rules (DTR) lG STU 2.0.0. URL: [Documentation Templates and Rules (FHIR IG) (hl7.org)](https://hl7.org/fhir/us/davinci-dtr/history.html)  HL7 FHIR Da Vinci Prior Authorization Support (PAS) IG STU  2.0.1. URL:  [[Da Vinci Prior Authorization Support (PAS) FHIR IG (hl7.org)](https://hl7.org/fhir/us/davinci-pas/history.html)](http://hl7.org/fhir/us/davinci-pas/history.html) |

\*We have made modifications to the required standards listed in this table from what was originally listed in Table 10 of the CMS Interoperability and Prior Authorization proposed rule (87 FR 76320).

\*\*We have removed the references to 45 CFR 170.215(c) SMART App Launch JG and 45 CFR 170.215(e) OpenTD Connect Core for the Provider Directory API that were mistakenly included in the proposed rule. Security protocols related to user authentication and authorization are excluded from the requirements for the Provider Directory APT (for MA organizations at 42 CFR 422.120 (a), for Medicaid at 42 CFR 43 l.70(a), and for CHIP at 42 CFR 457.760(a)). For more information see the discussion in the CMS Interoperability and Patient Access final rule at 85 FR 25560.

| **Changes/Potential Impact—As Finalized** | | |
| --- | --- | --- |
| **Changes Related to Part 422—Medicare Advantage Program** | | |
| **Change and Applicability Dates** | **Regulation Language (Revisions and Additions Only** | **CMS Discussion Highlights** |
| ***Amend §422.119 by—***   * In paragraph (b)(1)(ii), removing the word ‘‘and’’ at the end of the paragraph. * Revising paragraph (b)(1)(iii). * Adding paragraphs (b)(1)(iv) and (v). * Revising paragraphs (c)(1), (c)(4)(ii)(C), (e)(2), (f), and (h—Applicability Dates).   ***Applicability Dates:***  §422.119(e) and (g)—The effective date of the final rule.  §422.119(f)—Beginning January 1, 2026 | ***§422.119 Access to and exchange of health data and plan information.***  ***(b)(1)*** An MA organization must make the following information accessible to its current enrollees or the enrollee's personal representative through the API described in paragraph (a) of this section:  (iii)All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the MA organization no later than 1 business day after the MA organization receives the data; and  (iv) Beginning January 1, 2027, the information in paragraph (b)(1)(iv)(A) of this section about prior authorizations for items and services (excluding drugs, as defined in paragraph (b)(1)(v) of this section), according to the timelines in paragraph (b)(1)(iv)(B) of this section.  (A) The prior authorization request and decision, including all of the following, as applicable:  (*1*) The prior authorization status.  (*2*) The date the prior authorization was approved or denied.  (*3*) The date or circumstance under which the prior authorization ends.  (*4*) The items and services approved.  (*5*) If denied, a specific reason why the request was denied.  (*6*) Related structured administrative and clinical documentation submitted by a provider.  (B) The information in paragraph (b)(1)(iv)(A) of this section must—  (*1*) Be accessible no later than 1 business day after the MA organization receives a prior authorization request;  (*2*) Be updated no later than 1 business day after any status change; and  (*3*) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization’s last status change.  (v) Drugs are defined for the purposes of paragraph (b)(1)(iv) of this section as any and all drugs covered by the MA organization, including any products that constitute a Part D drug, as defined by §423.100 of this chapter, and are covered under the Medicare Part D benefit.  **(c)(1)** Must implement and maintain API technology conformant with 45 CFR  170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1).  **(c)(4)** May use an updated version of any standard or all standards required under paragraph (c)(1) or (3) of this section, where:  (ii) Use of the updated version of the standard is not prohibited under other applicable law, provided that:  (C) Using the updated version of the standard, implementation guide, or specification does not disrupt an end user’s ability to access the data specified in paragraph (b) of this section or §422.120, §422.121, and §422.122 through the required APIs.  **(e)(2)** Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to, criteria that rely on automated monitoring and risk mitigation tools.  **(f)** *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 following any calendar year that it offers an MA plan, an MA organization must report to CMS the following metrics, in the form of aggregated, de-identified data, for the previous calendar year at the contract level in the form and manner specified by the Secretary:  (1) The total number of unique enrollees whose data are transferred via the Patient Access API to a health app designated by the enrollee.  (2) The total number of unique enrollees whose data are transferred more than once via the Patient Access API to a health app designated by the enrollee. | Changes in this rule require the impacted payers (under 42 CFR Part 422—the MA organization; under 42 CFR Part 431—the state agency responsible for administering Medicaid and CHIP FFS; under Part 438—the Medicaid and/or CHIP MCO, PIHP, or PAHP) to implement and maintain a standards-based Patient Access Application Programming Interface (API). The Patient Access API must allow patients, through the health apps of their choice, to easily access their claims and encounter information as well as clinical data, including laboratory results, provider remittances, and patient cost-sharing pertaining to such claims, if maintained by the impacted payer.  ***D-SNP Comments (related to reporting on Patient usage of the Patient Access API):***  *Comment:* A few commenters requested that we explain whether integrated care plans for dually eligible individuals, such as fully integrated dual eligible special needs plans (FIDE SNPs), should report consistent with MA organizations, at the contract level, or with Medicaid managed care plans, at the plan level.  *Response:* An integrated care plan generally combines a dual eligible special needs plan (D–SNP), which includes FIDE SNPs and highly integrated dual eligible special needs  plans (HIDE SNPs)—both as defined at 42 CFR 422.2, and a Medicaid managed care plan offered by the same parent organization. **D–SNPs are a type of MA**  **plan** designed to meet the needs of individuals who are dually eligible for Medicare and Medicaid, also known as dually eligible individuals. Therefore, an MA organization will report information about Patient Access API usage by its D–SNP enrollees to CMS at the MA organization’s contract level. The affiliated Medicaid managed care plan will report information about Patient Access API usage by its enrollees to CMS at the plan level. We understand that this means an organization that offers an integrated product for dually eligible individuals (for example, a FIDE SNP), may report twice and in different ways for the same population. We do not believe this duplication outweighs the benefits of capturing the data as we proposed, but we may consider future rulemaking to separate reporting for integrated D–SNPs from the overall MA organization. |
| ***Adding §422.121*** | ***§422.121 Access to and exchange of health data for providers and payers.***  **(a)** *Application programming interface to support data exchange from payers to providers—Provider Access API.* Beginning January 1, 2027, an MA organization must do the following:  *(1) API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:  (i) Section 422.119(c)(2) through (4), (d), and (e).  (ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).  *(2) Provider access.* Make the data specified at §422.119(b) with a date of service on or after January 1, 2016, excluding provider remittances and enrollee cost-sharing information, that are maintained by the MA organization  available to in-network providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:  (i) The MA organization authenticates the identity of the provider that requests access and attributes the enrollee to the provider under the attribution process described in paragraph (a)(3) of this section.  (ii) The enrollee does not opt out as described in paragraph (a)(4) of this section.  (iii) Disclosure of the data is not prohibited by other applicable law.  (3) *Attribution.* Establish and maintain a process to associate enrollees  with their in-network providers to enable data exchange via the Provider Access API.  (4) *Opt out and patient educational resources.*  (i) Establish and maintain a process to allow an enrollee or the enrollee’s personal representative to opt out of the data exchange described in paragraph (a)(2) of this section and to change their permission at any time.  That process must be available before the first date on which the MA organization makes enrollee information available via the Provider Access API and at any time while the enrollee is enrolled with the MA organization.  (ii) Provide information to enrollees in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:  (A) Before the first date on which the MA organization makes enrollee information available through the Provider Access API.  (B) No later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.  (C) At least annually.  (D) In an easily accessible location on  its public website.  (5) *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting enrollee data using the Provider Access API required in paragraph (a)(1) of this section. The resources must include information about how to use the MA organization’s attribution process to associate enrollees with their providers.  (b) *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Beginning January 1, 2027, an MA organization must do the following:  (1) *API requirements.* Implement and maintain an API conformant with all of  the following:  (i) Section 422.119(c)(2) through (4), (d), and (e).  (ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).  (2) *Opt in.* Establish and maintain a process to allow enrollees or their personal representatives to opt into the MA organization’s payer to payer data exchange with the enrollee’s previous payer(s), described in paragraphs (b)(4) and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.  (i) The opt in process must be offered as follows:  (A) To current enrollees, no later than the compliance date.  (B) To new enrollees, no later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS,  whichever is later.  (ii) If an enrollee does not respond or additional information is necessary, the MA organization must make reasonable efforts to engage with the enrollee to collect this information.  (3) Identify *previous and concurrent payers.* Establish and maintain a process to identify a new enrollee’s previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:  (i) For current enrollees, no later than the compliance date.  (ii) For new enrollees, no later than 1 week after the coverage start date or no later than 1 week after receiving acceptance of enrollment from CMS, whichever is later.  (iii) If an enrollee does not respond or additional information is necessary, the MA organization must make reasonable efforts to engage with the enrollee to collect this information.  (4) *Exchange request requirements.* Exchange enrollee data with other  payers, consistent with the following requirements:  (i) The MA organization must request the data listed in paragraph (b)(4)(ii) of this section through the enrollee’s previous payers’ API, if all the following conditions are met:  (A) The enrollee has opted in, as described in paragraph (b)(2) of this section.  (B) The exchange is not prohibited by other applicable law.  (ii) The data to be requested are all of the following with a date of service within 5 years before the request:  (A) Data specified in §422.119(b) excluding the following:  (*1*) Provider remittances and enrollee cost-sharing information.  (*2*) Denied prior authorizations.  (B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.  (iii) The MA organization must include an attestation with this request affirming that the enrollee is enrolled with the MA organization and has opted into the data exchange.  (iv) The MA organization must complete this request as follows:  (A) No later than 1 week after the payer has sufficient identifying information about previous payers and the enrollee has opted in.  (B) At an enrollee’s request, within 1 week of the request.  (v) The MA organization must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the enrollee, any data made available by other payers in response to the request.  (5) *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the MA organization to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:  (i) The payer that requests access has itsidentity authenticated and includes an attestation with the request that the patient is enrolled with the payer and has opted into the data exchange.  (ii) Disclosure of the data is not prohibited by other applicable law.  (6) *Concurrent coverage data exchange requirements.* When an enrollee has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, an MA organization must do the following, through the API required in paragraph (b)(1) of this section:  (i) Request the enrollee’s data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the enrollee is enrolled with both payers.  (ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the MA organization may exclude any data that were previously sent to or originally received from the concurrent payer.  (7) *Patient educational resources.* Provide information to enrollees in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The MA organization must provide the following resources:  (i) When requesting an enrollee’s permission for Payer-to-Payer API data  exchange, as described in paragraph (b)(2) of this section.  (ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current enrollees.  (iii) In an easily accessible location on its public website. | Finalizing the rescission of the payer to payer data exchange policy previously finalized in the CMS Interoperability and Patient Access rule (85 FR 25568) at 42 CFR 422.119(f)(1) and 438.62(b)(1)(vi) and (vii) and 45 CFR 156.221(f)(1).  Finalizing the new standards beginning in 2027 (by January 1, 2027, for MA organizations and state Medicaid and CHIP FFS programs; by the rating period beginning on or after January 1, 2027, for Medicaid managed care plans and CHIP managed care entities; impacted payers must implement and maintain a Payer-to- Payer API that is conformant with certain technical standards, documentation requirements, and denial or discontinuation policies. Specifically, those technical standards are HL7 FHIR R4 at 45 CFR 170.215(a)(1), US Core IG at 45 CFR 170.215(b)(1)(i), and Bulk Data Access IG at 45 CFR 170.215(d)(1).  Finalizing our proposal that if a Medicaid or CHIP agency is exchanging information per our Payer to-Payer API proposals with a managed care plan or managed care entity with which they have a contract, the requirement to obtain patient opt in would not apply. We consider any plan and entity that has a contract with the state Medicaid or CHIP agency to deliver Medicaid program health care services to beneficiaries under the state plan, including state Medicaid agency contracts with **D– SNPs under 42 CFR 422.107**, to be part of the state’s Medicaid or CHIP programs, regardless of the coverage model. We note that this policy and opt in requirement to share data between impacted payers would  not replace regulatory requirements as described at 42 CFR part 422, including as they relate to integrated D–SNPs. |
| ***Adding §422.121*** | ***§422.121 Prior authorization requirements.***  **(a)** *Communicating a reason for denial.* Beginning January 1, 2026, if the MA organization denies a prior authorization request (excluding request for coverage of drugs as defined in §422.119(b)(1)(v)), in accordance with the timeframes established in §422.568(b)(1) and §422.572(a)(1), the response to the provider must include a specific reason for the denial, regardless of the method used to communicate that information.  **(b)** *Prior Authorization Application Programming Interface (API).* Beginning January 1, 2027, an MA organization must implement and maintain an API conformant with §422.119(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—  (1) Is populated with the MA organization’s list of covered items and services (excluding drugs, as defined in §422.119(b)(1)(v)) that require prior authorization;  (2) Can identify all documentation required by the MA organization for approval of any items or services that require prior authorization;  (3) Supports a Health Insurance Portability and Accountability Act (HIPAA)- compliant prior authorization request and response, as described in 45 CFR part 162; and  (4) Communicates the following information about prior authorization  requests:  (i) Whether the MA organization—  (A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);  (B) Denies the prior authorization request; or  (C) Requests more information.  (ii) If the MA organization denies the prior authorization request, it must include a specific reason for the denial.  (5) In addition to the requirements of this section, an MA organization using prior authorization polices or making prior authorization decisions must meet all other applicable requirements under this part, including §422.138 and the requirements in subpart M of this part.  **(c)** *Publicly reporting prior authorization metrics.* Beginning in 2026, following each calendar year that it offers an MA plan, an MA organization must report prior authorization data, excluding data on drugs as defined in §422.119(b)(1)(v), at the MA contract level by March 31. The MA organization must make the following data from the previous calendar year publicly accessible by posting them on its website:  (1) A list of all items and services that require prior authorization.  (2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.  (3) The percentage of standard prior authorization requests that were denied,  aggregated for all items and services.  (4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.  (5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.  (6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.  (7) The percentage of expedited prior authorization requests that were denied,  aggregated for all items and services.  (8) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations,  aggregated for all items and services.  (9) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services. | Because applicable integrated plans (**D–SNPs that have exclusively aligned enrollment with an affiliated Medicaid**  **MCO**) are a type of MA plan, the regulations regarding prior authorization processes that we are finalizing apply to them. The final rule revises the specific timeframes for prior authorization decisions by applicable integrated plans. Applicable integrated plans cover both Medicaid long term services and supports and MA benefits in ten states. Existing requirements already govern denial notices issued by applicable integrated plans to their enrollees and are similar to the Medicaid managed care and MA rules described in the prior paragraphs. Integrated organization determination notices must be written in plain language, available in a language and format that is accessible to the enrollee, and explain—   * The applicable integrated plan’s determination; * The date the determination was made; * The date the determination will take effect; * The reasons for the determination; * The enrollee’s right to file an integrated reconsideration and the ability for someone else to file an appeal on the enrollee’s behalf; * Procedures for exercising an enrollee’s rights to an integrated reconsideration; * The circumstances under which expedited resolution is available and how to request it; and * If applicable, the enrollee’s rights to have benefits continue pending the resolution of the integrated appeal process.   As with the notices required from MA plans, our finalized policies do not change the content requirements for these written denial notices to enrollees but will supplement these notices by requiring applicable integrated plans to notify the provider of the reason for a denial of a prior authorization request.  ***Comment regarding D-SNP reporting of prior authorization metrics:***  *Comment:* A commenter requested clarification on whether integrated care plans for dually eligible individuals, such as FIDE SNPs, should report these data consistent with MA organizations, at the contract level, or consistent with Medicaid managed care plans, at the plan level.  *Response:* Integrated care plans generally combine D–SNPs, which include FIDE SNPs and HIDE SNPs—both as defined at 42 CFR 422.2—and Medicaid managed care plans offered by the same parent organization. D–SNPs are a type of MA plan designed to meet the needs of individuals who are dually eligible for Medicare and Medicaid, also known as dually eligible individuals. In these arrangements, there is an MA organization with a contract with CMS for the MA D–SNP and an organization with a contact with the state for the Medicaid managed care plan. For items and services that require prior authorization under an integrated plan’s MA benefit package, data must be reported in a manner consistent with the requirements for MA organizations, which we are finalizing at the contract level. In the case of integrated care, the affiliated Medicaid managed care plan  will report prior authorizations of items  and services covered under the plan’s Medicaid benefit package at the plan level. Where there is not a clear delineation between whether items or services are covered under Medicare or Medicaid (for example, home health services), we will accept any reasonable methodology for attributing the prior authorization reporting to one payer versus the other. |
| ***Amend §422.568 by—***   * Revising paragraph (b)(1). * Redesignating paragraph (b)(2) as paragraph (b)(3). * Adding new paragraph (b)(2). * In newly redesignated paragraph (b)(3), removing the phrase ‘‘under the provisions in paragraph (b)(1)(i) of this section’’ and adding in its place the phrase ‘‘under the provisions in paragraph (b)(2) of this section.’’ | ***§422.568 Standard timeframes and notice requirements for organization determinations.***  **(b)(1)** *Requests for service or item.* Except as provided in paragraph (b)(2) of this section, when a party has made a request for an item or service, the MA  organization must notify the enrollee of its determination as expeditiously as the enrollee’s health condition requires but no later than either of the following:  (i) For a service or item not subject to the prior authorization rules in §422.122, 14 calendar days after receiving the request for the standard organization determination.  (ii) Beginning on or after January 1, 2026, for a service or item subject to the prior authorization rules in §422.122, 7 calendar days after receiving the request for the standard organization determination.  (2) *Extensions; requests for service or item*—  (i) Extension *of timeframe on a request for service or item.* The MA organization may extend the timeframe by up to 14 calendar days under any of the following circumstances:  (A) The enrollee requests the extension.  (B) The extension is justified and in the enrollee’s interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization’s decision to deny an item or service.  (C) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee’s interest.  (ii) Notice *of extension.*  (A) When the MA organization extends the timeframe, it must—  (*1*) Notify the enrollee in writing of the reasons for the delay; and  (*2*) Inform the enrollee of the right to file an expedited grievance if the enrollee disagrees with the MA organization’s decision to grant an extension.  (B) The MA organization must notify the enrollee of its determination as expeditiously as the enrollee’s health condition requires, but no later than upon expiration of the extension. | Under the existing MA rules, a failure to meet the deadline by which an organization determination, including a request for prior authorization, constitutes a denial that can be appealed to the next level (reconsideration by the MA organization). See 42 CFR 422.568(f) and 422.631(d)(1)(ii). The MA program regulations (42 CFR 422.592 through 422.596 and 422.634) provide for review by an Independent Review Entity (IRE) after an MA organization’s adverse reconsidered organization determination, including where the MA organization fails to issue a reconsidered organization determination in a timely fashion. We did not propose, and are therefore not finalizing here, an amendment to those rules to escalate prior authorization denials to the IRE. |
| ***Amend §422.570 by—***  In paragraph (d)(1) by removing the phrase ‘‘request to the standard timeframe and make the determination within the 72-hour or 14-day timeframe, as applicable, established’’ and adding in its place the phrase ‘‘request to a standard organization determination and make the determination within the applicable timeframe, established’’. | ***§422.570 Expediting certain organization determinations.***  (d) *Actions following denial*. (1) Automatically transfer a request to a standard organization determination and make the determination within the applicable timeframe, established in §422.568 for a standard determination. The timeframe begins when the MA organization receives the request for expedited determination. |  |
| ***Amend §422.631 by—***  Revising paragraphs:   * (d)(2)(i)(B). * (d)(2)(iv)(B)(*1*). * (d)(2)(iv)(B)(*2*)(*i*) | ***§422.631 Integrated organization determinations.***  **(d)(2)(i)(A)** The applicable integrated plan must send a notice of its integrated organization determination at least 10 days before the date of action (that is, before the date on which a termination, suspension, or reduction becomes effective), in cases where a previously approved service is being reduced, suspended, or terminated, except in circumstances where an exception is permitted under §431.213 and §431.214 of this chapter.  **(d)(2)(i)(B)** Except as described in paragraph (d)(2)(i)(A) of this section, the  applicable integrated plan must send a notice of its integrated organization determination as expeditiously as the enrollee’s health condition requires but no later than either of the following:  (*1*) For a service or item not subject to the prior authorization rules in §422.122, 14 calendar days after receiving the request for the standard integrated organization determination.  (*2*) Beginning on or after January 1, 2026, for a service or item subject to the prior authorization rules in §422.122, 7 calendar days after receiving the request for the standard integrated organization determination.  (iv)(B)  (*1*) Automatically transfer a request to the standard timeframe and make the determination within the applicable timeframe established in paragraph (d)(2)(i)(B) of this section for a standard integrated organization determination.  The timeframe begins the day the applicable integrated plan receives the request for expedited integrated organization determination.  (*2*)(*i*) Explains that the applicable integrated plan will process the request using the timeframe for standard integrated organization determinations. |  |

| **Changes/Potential Impact—As Finalized** | | |
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| **Changes Related to Part 431—State Organizational and General Administration** | | |
| **Change and Applicability Dates** | **Regulation Language (Revisions and Additions Only** | **CMS Discussion Highlights** |
| ***Amend §431.60 by—***   * Revising paragraph (b)(3). * Adding paragraphs (b)(5) and (6). * Revising paragraphs (c)(1), (c)(4)(ii)(C), and (e)(2). * Removing paragraph (g). * Redesignating paragraph (f) as paragraph (g). * Adding new paragraph (f) and paragraph (h—applicability).   ***Applicability Date:***  A state must comply with the requirements in paragraphs (a) through (e) and (g) of this section beginning January 1, 2021, and with the requirements in paragraph (f) of this section beginning in 2026, with regard to data:  (1) With a date of service on or after January 1, 2016; and  (2) That are maintained by the state. | ***§431.60 Beneficiary access to and exchange of data.***  **(b)(3)** All data classes and data elements included in a content standard in 45 CFR 170.213 that are maintained by the state no later than 1 business day after the state receives the data.  **(b)(5)** Beginning January 1, 2027, the information in paragraph (b)(5)(i) of this section about prior authorizations for items and services (excluding drugs as defined in paragraph (b)(6) of this section), according to the timelines in paragraph (b)(5)(ii) of this section.  (i) The prior authorization request and decision, including all of the following, as applicable:  (A) The prior authorization status.  (B) The date the prior authorization was approved or denied.  (C) The date or circumstance under which the prior authorization ends.  (D) The items and services approved.  (E) If denied, a specific reason why the request was denied.  (F) Related structured administrative and clinical documentation submitted by a provider.  (ii) The information in paragraph (b)(5)(i) of this section must—  (A) Be accessible no later than 1 business day after the state receives a prior authorization request.  (B) Be updated no later than 1 business day after any status change.  (C) Continue to be accessible for the duration that the authorization is active and at least 1 year after the prior authorization’s last status change.  **(b)(6)** Drugs are defined for the purposes of paragraph (b)(5) of this section as any and all drugs covered by the state.  **(c)(1)** Must implement and maintain application programming interface (API) technology conformant with 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (e)(1).  **(c)(4)(ii)(C)** Using the updated version of the standard, implementation guide, or specification does not disrupt an end user’s ability to access the data specified in paragraph (b) of this section or §431.61, §431.70, and §431.80, through the required APIs.  **(e)(2)** Makes this determination using objective, verifiable criteria that are applied fairly and consistently across all apps and developers through which parties seek to access electronic health information, as defined in 45 CFR 171.102, including but not limited to criteria that rely on automated monitoring and risk mitigation tools.  **(f)** *Reporting on Patient Access API usage.* Beginning in 2026, by March 31 of each year, a state must report to CMS the following metrics, in the form of aggregated, de-identified data, for the previous calendar year at the state level in the form and manner specified by the Secretary:  **(f)(1)** The total number of unique beneficiaries whose data are transferred via the Patient Access API to a health app designated by the beneficiary.  **(f)(2)** The total number of unique beneficiaries whose data are transferred more than once via the Patient Access API to a health app designated by the beneficiary. | The initial rule required that Patient Access APIs include claims, encounter, and clinical data. This rule requires that payers now include prior authorization information and adds requirements for reporting metrics to CMS. (One year of historical prior authorization data required on the Patient Access API.)  Patients are permitted to opt out. |
| ***Adding §431.61***  ***Applicability Date:***  January 1, 2027 | ***§431.61*(a)** ***Application programming interface to support data exchange from payers to providers—Provider Access API.***Beginning January 1, 2027, unless granted an extension or exemption under paragraph (c) of this section, a state must do the following:  **(a)(1)** *API requirements.* Implement and maintain an application programming interface (API) conformant with all of the following:  (i) Section 431.60(c)(2) through (4), (d), and (e).  (ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), (c)(1), and (d)(1).  **(a)(2)** *Provider access.* Make the data specified in §431.60(b) with a date of service on or after January 1, 2016, excluding provider remittances and beneficiary cost-sharing information, that are maintained by the state available to enrolled Medicaid providers via the API required in paragraph (a)(1) of this section no later than 1 business day after receiving a request from such a provider, if all the following conditions are met:  (i) The state authenticates the identity of the provider that requests access and attributes the beneficiary to the provider under the attribution process described in paragraph (a)(3) of this section.  (ii) The beneficiary does not opt out as described in paragraph (a)(4) of this section.  (iii) Disclosure of the data is not prohibited by other applicable law.  **(a)(3)** *Attribution.* Establish and maintain a process to associate beneficiaries with their enrolled Medicaid providers to enable data exchange via the Provider Access API.  **(a)(4)** *Opt out and patient educational resources.*  (i) Establish and maintain a process to allow a beneficiary or the beneficiary’s personal representative to opt out of the data exchange described in paragraph (a)(2) of this section and to change their permission at any time. That process must be available before the first date on which the state makes beneficiary information available via the Provider Access API and at any time while the beneficiary is enrolled with the state.  (ii) Provide information to beneficiaries in plain language about the benefits of API data exchange with their providers, their opt out rights, and instructions both for opting out of data exchange and for subsequently opting in, as follows:  (A) Before the first date on which the state makes beneficiary information available through the Provider Access API.  (B) No later than 1 week after enrollment.  (C) At least annually.  (D) In an easily accessible location on its public website.  **(a)(5)** *Provider resources.* Provide on its website and through other appropriate provider communications, information in plain language explaining the process for requesting beneficiary data using the Provider Access API required in paragraph (a)(1) of this section. The resources must include information about how to use the state’s attribution process to associate beneficiaries with their providers.  **(b)** *Application programming interface to support data exchange between payers—Payer-to-Payer API.* Beginning January 1, 2027, unless granted an extension or exemption under paragraph (c) of this section, a state must do the following:  **(b)(1)** *API requirements.* Implement and maintain an API conformant with all of the following:  (i) Section 431.60(c)(2) through (4), (d), and (e).  (ii) The standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (d)(1).  **(b)(2)** *Opt in.* Establish and maintain a process to allow beneficiaries or their personal representatives to opt into the state’s payer to payer data exchange with the beneficiary’s previous payer(s), described in paragraphs (b)(4) and (5) of this section, and with concurrent payer(s), described in paragraph (b)(6) of this section, and to change their permission at any time.  (i) The opt in process must be offered as follows:  (A) To current beneficiaries, no later than the compliance date.  (B) To new beneficiaries, no later than 1 week after enrollment.  (ii) If a beneficiary has coverage through any Medicaid MCO, prepaid inpatient health plan (PIHP), or prepaid ambulatory health plan (PAHP) within the same state while enrolled in Medicaid, the state must share their opt in permission with those MCO, PIHP, or PAHP to allow the Payer-to-Payer API data exchange described in this section.  (iii) If a beneficiary does not respond or additional information is necessary, the state must make reasonable efforts to engage with the beneficiary to collect this information.  **(b)(3)** *Identify previous and concurrent payers.* Establish and maintain a process to identify a new beneficiary’s previous and concurrent payer(s) to facilitate the Payer-to-Payer API data exchange. The information request process must start as follows:  (i) For current beneficiaries, no later than the compliance date.  (ii) For new beneficiaries, no later than 1 week after enrollment.  (iii) If a beneficiary does not respond or additional information is necessary, the state must make reasonable efforts to engage with the beneficiary to collect this information.  **(b)(4)** *Exchange request requirements.* Exchange beneficiary data with other payers, consistent with the following requirements:  (i) The state must request the data specified in paragraph (b)(4)(ii) of this section through the beneficiary’s previous payers’ API, if all the following conditions are met:  (A) The beneficiary has opted in, as described in paragraph (b)(2) of this section, except for data exchanges between a state Medicaid agency and its contracted MCOs, PIHPs, or PAHPs, which do not require a beneficiary to  opt in.  (B) The exchange is not prohibited by other applicable law.  (ii) The data to be requested are all of the following with a date of service within 5 years before the request:  (A) Data specified in §431.60(b), excluding the following:  (*1*) Provider remittances and enrollee cost-sharing information.  (*2*) Denied prior authorizations.  (B) Unstructured administrative and clinical documentation submitted by a provider related to prior authorizations.  (iii) The state must include an attestation with this request affirming that the beneficiary is enrolled with the state and has opted into the data exchange.  (iv) The state must complete this request as follows:  (A) No later than 1 week after the payer has sufficient identifying information about previous payers and the beneficiary has opted in.  (B) At a beneficiary’s request, within 1 week of the request.  (v) The state must receive, through the API required in paragraph (b)(1) of this section, and incorporate into its records about the beneficiary, any data made available by other payers in response to the request.  **(b)(5)** *Exchange response requirements.* Make available the data specified in paragraph (b)(4)(ii) of this section that are maintained by the state to other payers via the API required in paragraph (b)(1) of this section within 1 business day of receiving a request, if all the following conditions are met:  (i) The payer that requests access has its identity authenticated and includes an attestation with the request that the patient is enrolled with the payer and has opted into the data exchange.  (ii) Disclosure of the data is not prohibited by other applicable law.  **(b)(6)** *Concurrent coverage data exchange requirements.* When a beneficiary has provided sufficient identifying information about concurrent payers and has opted in as described in paragraph (b)(2) of this section, a state must do the following, through the API required in paragraph (b)(1) of this section:  (i) Request the beneficiary’s data from all known concurrent payers as described in paragraph (b)(4) of this section, and at least quarterly thereafter while the beneficiary is enrolled with both payers.  (ii) Respond as described in paragraph (b)(5) of this section within 1 business day of a request from any concurrent payers. If agreed upon with the requesting payer, the state may exclude any data that were previously sent to or originally received from the concurrent payer.  **(b)(7)** *Patient educational resources.* Provide information to applicants or beneficiaries in plain language, explaining at a minimum: the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw that permission, and instructions for doing so. The state must provide the following resources:  (i) When requesting a beneficiary’s permission for Payer-to-Payer API data exchange, as described in paragraph (b)(2) of this section.  (ii) At least annually, in appropriate mechanisms through which it ordinarily communicates with current beneficiaries.  (iii) In an easily accessible location on  its public website.  **(c)** *Extensions and exemptions*—  **(c)(1)** *Extension.*  (i) A state may submit a written application to request a onetime, 1-year extension of the requirements in paragraph (a) or (b) of this section (or paragraphs (a) and (b)) for its Medicaid fee-for-service (FFS) program. The written application must be submitted as part of the state’s annual Advance Planning Document (APD) for Medicaid Management Information System (MMIS) operations expenditures described in part 433, subpart C, of this chapter, and approved before the compliance date for the requirements to which the state is seeking an extension. It must include all the following:  (A) A narrative justification describing the specific reasons why the state cannot satisfy the requirement(s) by the compliance date and why those reasons result from circumstances that are unique to the agency operating the Medicaid FFS program.  (B) A report on completed and ongoing state activities that evidence a good faith effort towards compliance.  (C) A comprehensive plan to meet the requirements no later than 1 year after the compliance date.  (ii) CMS grants the state’s request if it determines, based on the information  provided, that—  (A) The request adequately establishes a need to delay implementation; and (B) The state has a comprehensive plan to meet the requirements no later than 1 year after the compliance date.  **(c)(2)** *Exemption.*  (i) A state operating a Medicaid program in which at least 90 percent of the state’s Medicaid beneficiaries are enrolled in Medicaid managed care organizations, as defined in §438.2 of this chapter, may request an exemption for its FFS program from either or both of the following  requirement(s):  (A) Paragraph (a) of this section.  (B) Paragraphs (b)(1) and (3) through (7) of this section.  (ii) The state’s exemption request must:  (A) Be submitted in writing as part of a state’s annual APD for MMIS operations expenditures before the compliance date for the requirements to which the state is seeking an exemption.  (B) Include both of the following:  (*1*) Documentation that the state meets the threshold for the exemption, based on enrollment data from the most recent CMS ‘‘Medicaid Managed Care Enrollment and Program Characteristics’’ (or successor) report.  (*2*) An alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.  (iii) CMS grants the exemption if the state establishes to CMS’s satisfaction that the state—  (A) Meets the threshold for the exemption; and  (B) Has established an alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.  (iv) The state’s exemption expires if either—  (A) Based on the 3 previous years of available, finalized Medicaid Transformed Medicaid Statistical Information System (T–MSIS) managed care and FFS enrollment data, the state’s managed care enrollment for 2 of the previous 3 years is below 90 percent; or  (B)(*1*) CMS has approved a state plan amendment, waiver, or waiver amendment that would significantly reduce the percentage of beneficiaries enrolled in managed care; and  (*2*) The anticipated shift in enrollment is confirmed by the first available, finalized Medicaid T–MSIS managed care and FFS enrollment data.  (v) If a state’s exemption expires under paragraph (c)(2)(iv) of this section, the state is required to do both of the following—  (A) Submit written notification to CMS that the state no longer qualifies for the exemption within 90 days of the finalization of annual Medicaid T–MSIS managed care enrollment data that demonstrates that there has been the requisite shift from managed care enrollment to FFS enrollment resulting in the state’s managed care enrollment falling below the 90 percent threshold.  (B) Obtain CMS approval of a timeline for compliance with the requirements in paragraph (a) or (b) (or paragraph0s (a) and (b)) of this section within 2 years of the expiration of the exemption. | Provider Access API is new in this rule and requires payer to provider and payer to payer exchange of information through a Provider Access API.   * At least quarterly. * Back to service date of January 1, 2016 (except prior authorization data, which is one year). * Payers must respond to a request for patient data via the Provider Access API within one business day of the request. * While Patient Access and Provider Access APIs use and opt out approach, opt in approach is used for the payer to payer API (except in Medicaid and CHIP managed care).   Notes:   * Only “In-network or enrolled providers with a verified treatment relationship to the patient”. * This is a requirement for the payers, and although payers are not required to compel providers to use it, states may choose to add requirements to contracts. |
| ***Adding §431.80***  ***Applicability Date:***  states to include specific reason for denial in communications—January 1, 2026.  To include specific reason for denial in the Patient Access API—January 1, 2027.  Prior Authorization API—January 1, 2027. | ***§431.80 Prior authorization requirements.***  **(a)** *Communicating a reason for denial.* Beginning January 1, 2026, if the state denies a prior authorization request (excluding a request for coverage of drugs as defined in §431.60(b)(6)), in accordance with the timeframes established in §440.230(e)(1) of this chapter, the response to the provider must include a specific reason for the denial, regardless of the method used to communicate that information.  **(b)** *Prior Authorization Application Programming Interface (API).* Unless granted an extension or exemption under paragraph (c) of this section, beginning January 1, 2027, a state must implement and maintain an API conformant with §431.60(c)(2) through (4), (d), and (e), and the standards in 45 CFR 170.215(a)(1), (b)(1)(i), and (c)(1) that—  (1) Is populated with the state’s list of covered items and services (excluding drugs, as defined in §431.60(b)(6)) that require prior authorization;  (2) Can identify all documentation required by the state for approval of any items or services that require prior authorization;  (3) Supports a HIPAA-compliant prior authorization request and response, as described in 45 CFR part 162; and (4) Communicates the following information about prior authorization requests:  (i) Whether the state—  (A) Approves the prior authorization request (and the date or circumstance under which the authorization ends);  (B) Denies the prior authorization request; or  (C) Requests more information.  (ii) If the state denies the prior authorization request, it must include a specific reason for the denial.  **(c)** *Extensions and exemptions*—  **(c)(1)** *Extension.*  (i) A state may submit a written application to request a onetime, 1-year extension of the requirements in paragraph (b) of this section for its Medicaid FFS program. The written application must be submitted as part of the state’s annual APD for MMIS operations expenditures described in part 433, subpart C, of this chapter; and approved before the compliance date in paragraph (b) of this section. It must include all the following:  (A) A narrative justification describing the specific reasons why the state cannot satisfy the requirement(s) by the compliance date and why those reasons result from circumstances that are unique to the agency operating the Medicaid FFS program. (B) A report on completed and ongoing state activities that evidence a good faith effort towards compliance.  (C) A comprehensive plan to meet the requirements no later than 1 year after the compliance date.  (ii) CMS grants the state’s request if it determines, based on the information provided, that—  (A) The request adequately establishes a need to delay implementation; and  (B) The state has a comprehensive plan to meet the requirements no later than 1 year after the compliance date.  **(c)(2)** *Exemption.*  (i) A state operating a Medicaid program in which at least 90 percent of the state’s Medicaid beneficiaries are enrolled in Medicaid managed care organizations, as defined in §438.2 of this chapter, may request an exemption for its FFS program from the requirements in paragraph (b) of this section.  (ii) The state’s exemption request must:  (A) Be submitted in writing as part of a state’s annual APD for MMIS operations expenditures before the compliance date in paragraph (b) of this section.  (B) The state’s request must include both of the following:  (*1*) Documentation that the state meets the threshold for the exemption, based on enrollment data from the most recent CMS ‘‘Medicaid Managed Care Enrollment and Program Characteristics’’ (or successor) report.  (*2*) An alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.  (iii) CMS grants the exemption if the state establishes to CMS’s satisfaction that the state—  (A) Meets the threshold for the exemption; and  (B) Has established an alternative plan to ensure that enrolled providers will have efficient electronic access to the same information through other means while the exemption is in effect.  (iv) The state’s exemption expires if either—  (A) Based on the 3 previous years of available, finalized Medicaid Transformed Medicaid Statistical Information System (T–MSIS) managed care and FFS enrollment data, the state’s managed care enrollment for 2 of the previous 3 years is below 90 percent; or (B)(*1*) CMS has approved a state plan amendment, waiver, or waiver amendment that would significantly reduce the percentage of beneficiaries enrolled in managed care; and  (*2*) The anticipated shift in enrollment is confirmed by the first available, finalized Medicaid T–MSIS managed care and FFS enrollment data.  (v) If a state’s exemption expires under paragraph (c)(2)(iv) of this section, the state is required to do both of the following—  (A) Submit written notification to CMS that the state no longer qualifies for the exemption within 90 days of the finalization of annual Medicaid T–MSIS managed care enrollment data that demonstrates that there has been the requisite shift from managed care enrollment to FFS enrollment resulting in the state’s managed care enrollment falling below the 90 percent threshold.  (B) Obtain CMS approval of a timeline for compliance with the requirements in paragraph (b) of this section within 2 years of the expiration of the exemption. | Requires payers to communicate the specific reason for the denial regardless of the communication method used. Some payers subject to this requirement will also remain subject to existing requirements to provide notice to patients, providers, or both, with the specific reasons for the denial.  In addition, for certain payers impacted by this final rule, existing communication requirements related to coverage decisions, notices of coverage decisions, and appeal processes, remain in effect for coverage decisions that are made as part of a prior authorization denial or approval. These requirements are not changed under this final rule (does not apply to prior authorization of prescription drugs). We also remind all Medicaid managed care plans and CHIP managed care entities subject to this final rule that their existing obligations to provide these required notices to patients are not changed by the final policies in this rule.  Requires the impacted payer to maintain a Prior Authorization API. Prior authorization of prescription drugs is excluded from the Prior Authorization API.  Providers can use the Prior Authorization API to determine whether a specific payer requires prior authorization for a certain item or service, thereby easing one of the major points of administrative burden in the existing prior authorization process. The Prior Authorization API will also allow providers to query the payer’s prior authorization documentation requirements directly from the provider’s system, which could facilitate the automated compilation of necessary information to submit a prior authorization request. |
| ***Amend §431.201 by—***  Revising the definition of ‘‘Action’’.  ***Applicability Date:***  The effective date of the final rule. | ***§431.201 Definitions.***  ***Action***means one of the following:  (1) A termination, suspension of, or reduction in covered benefits or services, including benefits or services for which there is a current approved prior authorization;  (2) A termination, suspension of, or reduction in Medicaid eligibility, or an increase in beneficiary liability, including a determination that a beneficiary must incur a greater amount of medical expenses to establish income eligibility in accordance with §435.121(e)(4) or §435.831 of this chapter;  (3) A determination that a beneficiary is subject to an increase in premiums or cost-sharing charges under subpart A of part 447 of this chapter; or  (4) A determination by a skilled nursing facility or nursing facility to transfer or discharge a resident and an adverse determination by a state regarding the preadmission screening and resident review requirements of section 1919(e)(7) of the Act. | ***Note:*** Terminology used in Medicaid and CHIP FFS programs continue to differ from terminology used in managed care programs (e.g., action, notice of adverse benefit determination). |
| ***Amend §431.220 by—***   * In paragraph (a)(1)(iv), removing the term ‘‘or’’ from the end of the paragraph. * In paragraph (a)(1)(v), removing the period from the end of the paragraph and adding in its place ‘‘; or’’. * Adding paragraph (a)(1)(vi).   ***Applicability Date:***  The effective date of the final rule. | ***§431.220 When a hearing is required.***  (a)(1) (vi) A prior authorization decision. | A commenter stated that there needs to be more clarification in the rule that existing Medicaid beneficiary notice and fair hearing rights apply to prior authorization decisions for Medicaid FFS beneficiaries.  *Response:* The existing requirements for the fair hearing process at 42 CFR part 431, subpart E, apply to Medicaid FFS prior authorization fair hearings. |

| **Changes/Potential Impact—As Finalized** | | |
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| **Changes Related to Part 435—Eligibility** | | |
| **Change and Applicability Dates** | **Summary of Changes** | **CMS Discussion Highlights** |
| ***Amend §435.917 by—***   * Revising the headings of paragraphs (a) and (b). * Revising paragraph (b)(2).   ***Applicability Date:***  The effective date of the final rule. | ***§435.917 Notice of agency’s decision concerning eligibility, benefits, or services.***  **(a)** *Notice of determinations.*  **(b)** *Content of notice*—  **(b)(2)** *Notice of adverse action.* Notice of adverse action including denial, termination, or suspension of eligibility or change in benefits or services. Any notice of denial, termination, or suspension of Medicaid eligibility, or, in the case of beneficiaries receiving medical assistance, denial of or change in benefits or services must be consistent with §431.210 of this chapter. | The Medicaid notice and fair hearing provisions at 42 CFR 435.917 and 42 CFR part 431, subpart E, which are cross referenced at 42 CFR 440.230(e)(2), apply to applicants and beneficiaries, not providers. |

| **Changes/Potential Impact—As Finalized** | | | |
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| **Changes Related to Part 438—Managed Care** | | | |
| **Change and Applicability Dates** | **Summary of Changes** | **CMS Discussion Highlights** | **CHIP Cross Reference** |
| ***Amend §438.9 by—***   * Revising paragraph (b)(7).   ***Applicability Date:***  January 1, 2027. | ***§438.9(b)(7)*** The PAHP standards in §438.206(b)(1), §438.210, §438.214, §438.224, §438.230, and §438.242, excluding the requirement in §438.242(b)(7), to comply with §431.61(a) and (b) of this chapter. | PAHPs are required to comply with this rule (except FFS NEMT PAHPs). | The policies in the CMS Interoperability and Patient Access final rule (85 FR 25559) are applicable to separate CHIP managed care entities per 42 CFR 457.1233(d) through a cross reference to Medicaid managed care at 42 CFR 438.242. We apply the API requirements in this final rule to separate CHIP managed care entities through the existing cross reference at 42 CFR 457.1233(d) to Medicaid managed care at 42 CFR 438.242.  The proposed rule that the proposal to amend 42 CFR 438.210(d) for timeframes would also apply to standard and expedited decisions made by CHIP managed care entities because of the cross reference to 42 CFR 438.210 in current 42 CFR 457.1230(d). |
| ***Amend §438.62 by—***   * Removing paragraphs (b)(1)(vi) and (vii).   ***Applicability Date:***  January 1, 2027. | ***§438.62*** | Given the concerns raised by stakeholders regarding the lack of technical specification in our previously finalized policy, we are finalizing the proposal to rescind the payer to payer data exchange policy finalized in the CMS Interoperability and Patient Access rule (85 FR 25568) at 42 CFR 422.119(f)(1) and 438.62(b)(1)(vi) and (vii) and 45 CFR 156.221(f)(1). We did so to prevent industry from developing multiple systems, and to help payers avoid the costs of developing non-standardized, non-API systems, and the challenges associated with those systems. We proposed (and a finalizing) a new policy that would, instead, require impacted payers to implement and maintain a Payer-to-Payer API using the FHIR standard. We stated that using FHIR APIs would ensure greater uniformity and ultimately lead to payers having more complete information available to share with patients and providers. |
| ***Amend §438.210 by—***   * Revising paragraphs (d)(1) and (d)(2)(i). * Redesignating paragraph (f) as paragraph (g). * Adding new paragraph (f).   ***Applicability Date:***  January 1, 2026 | ***§438.210 Coverage and authorization of services.***  **(d)(1)** *Standard authorization decisions.*  (i) For standard authorization decisions, provide notice as expeditiously as the enrollee’s condition requires and:  (A) For rating periods that start before January 1, 2026, within state established time frames that may not exceed 14 calendar days after receiving the request for service.  (B) For rating periods that start on or after January 1, 2026, within state established time frames that may not exceed 7 calendar days after receiving the request for service.  (ii) Standard authorization decisions may have an extension to the timeframes in paragraph (d)(1)(i) of this section up to 14 additional calendar days if—  (A) The enrollee or the provider requests the extension; or  (B) The MCO, PIHP, or PAHP justifies (to the state agency upon request) a need for additional information and how the extension is in the enrollee’s interest.  **(d)(2)**  (i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee’s life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee’s health condition requires and no later than 72 hours after receipt of the request for service.  **(f)** *Publicly reporting prior authorization metrics.* Beginning January 1, 2026, following each calendar year it has a contract with a state Medicaid agency, the MCO, PIHP, or PAHP must report prior authorization data, excluding data on any and all drugs covered by the MCO, PIHP, or PAHP, at the plan level by March 31. The MCO, PIHP, or PAHP must make the following data from the previous calendar year publicly accessible by posting them on its website:  (1) A list of all items and services that require prior authorization.  (2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.  (3) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.  (4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.  (5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.  (6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.  (7) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.  (8) The average and median time that elapsed between the submission of a request and a determination by the MCO, PIHP or PAHP, for standard prior authorizations, aggregated for all items and services.  (9) The average and median time that elapsed between the submission of a request and a decision by the MCO, PIHP or PAHP, for expedited prior authorizations, aggregated for all items and services. | Our proposal would not change the current provisions for how failure to issue a decision within the required timeframe constitutes an adverse benefit determination that can be appealed under 42 CFR 438.404(c)(5). The regulations at 42 CFR 438.404 and other regulations governing appeal rights at 42 CFR part 438, subpart F, would continue to apply and we did not propose to amend those regulations. We note that 42 CFR 438.404(c)(3) through (6) provide that certain adverse benefit determinations must be issued on the timing specified at 42 CFR 422.210(d); the new timeframes proposed (and finalized) in this rulemaking will apply to those specific adverse benefit determinations. In addition, under current regulations at 42 CFR 438.3(s)(1) and (6) and 438.210(d)(3), Medicaid managed care plans must also comply with the requirements regarding coverage and prior authorization of covered outpatient drugs; nothing in this rulemaking would change these requirements. Finally, because some Medicaid MCOs are applicable integrated plans as defined at 42 CFR 438.2, our proposal related to 42 CFR 422.631(d) applied to those plans. |
| ***Amend §438.242 by—***   * Revising paragraph (b)(5). * Adding paragraphs (b)(7) through (9).   ***Applicability Date:***  January 1, 2027. | ***§438.242 Health information systems.***  **(b)(5)** Subject to paragraph (b)(8) of this section, implement and maintain a Patient Access Application Programming Interface (API) required in §431.60 of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP and:  (i) Include all encounter data, including encounter data from any network providers the MCO, PIHP, or PAHP is compensating based on capitation payments and adjudicated claims and encounter data from any subcontractors.  (ii) Exclude covered outpatient drugs as defined in section 1927(k)(2) of the Act.  (iii) Report metrics specified in §431.60(f) of this chapter at the plan level.  **(b)(7)** By the rating period beginning on or after January 1, 2027, comply with §431.61(a), (b)(1) and (4) through (6), and (b)(7)(ii) and (iii) and §431.80(b) of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP  **(b)(8)** By the rating period beginning on or after January 1, 2026, comply with §431.80(a) of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP according to the decision timeframes in §438.210(d).  **(b)(9)** The following timeframes apply to paragraph (b)(5) of this section:  (i) Except for the requirements in §431.60(b)(5), (g), and (h) of this chapter, comply with the requirements of §431.60 of this chapter by January 1, 2021.  (ii) Comply with the requirements in §431.60(b)(5) and (g) of this chapter by the rating period beginning on or after January 1, 2026.  (iii) Beginning in 2026, by March 31 following any year the MCO, PIHP, or PAHP operates, comply with the reporting requirements in §431.60(h) of this chapter for the previous calendar year’s data, in the form of aggregated, de-identified metrics, at the plan level. |  |

| **Changes/Potential Impact—As Finalized** | | |
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| **Changes Related to Part 440—General Provisions** | | |
| **Change and Applicability Dates** | **Summary of Changes** | **CMS Discussion Highlights** |
| ***Amend §440.230 by—***  Adding paragraph (e).  ***Applicability Date:***  January 1, 2026. | ***§440.230*(e)** For prior authorization requests for items and services (excluding drugs, as defined in §431.60(b)(6) of this chapter), the state Medicaid agency  must—  **(e)(1)** Beginning January 1, 2026, make prior authorization decisions within the following timeframes:  (i) For a standard determination, as expeditiously as a beneficiary’s health condition requires, but in no case later than 7 calendar days after receiving the request, unless a shorter minimum timeframe is established under state law. The timeframe for standard authorization decisions can be extended by up to 14 calendar days if the beneficiary or provider requests an extension, or if the state agency determines that additional information from the provider is needed to make a decision.  (ii) For an expedited determination, as expeditiously as a beneficiary’s health condition requires, but in no case later than 72 hours after receiving the request, unless a shorter minimum timeframe is established under state law.  **(e)(2)** Provide the beneficiary with notice of the agency’s prior authorization decision in accordance with §435.917 of this chapter and provide fair hearing rights, including advance notice, in accordance with part 431, subpart E, of this chapter.  **(e)(3)** Beginning in 2026, annually report prior authorization data, excluding data on drugs, as defined in §431.60(b)(6) of this chapter, at the state level by March 31. The state must make the following data from the previous calendar year publicly accessible by posting them on its website:  (i) A list of all items and services that require prior authorization.  (ii) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.  (iii) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.  (iv) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.  (v) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.  (vi) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.  (vii) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.  (viii) The average and median time that elapsed between the submission of a request and a determination by the state Medicaid agency, for standard prior authorizations, aggregated for all items and services.  (ix) The average and median time that elapsed between the submission of a request and a decision by the state Medicaid agency for expedited prior authorizations, aggregated for all items and services. | Timeframes for prior authorization decisions under the Medicaid FFS program have been newly established with this final rule. The timeframe for standard authorization decisions can be extended by up to 14 calendar days if the beneficiary or provider requests an extension or if the state agency determines that additional information from the provider is needed to make a decision.  The Medicaid notice requirements are separate from and independent of, the new timeline for provider notice that is finalized at 42 CFR 440.230(e)(1).  To make it explicit that existing Medicaid beneficiary notice and fair hearing rights apply to Medicaid FFS prior authorization decisions, we proposed several updates to the existing regulations at 42 CFR 431.201, 431.220, and 435.917, and a new 42 CFR 440.230(e)(2). The proposed changes are intended to further explain, but not change, Medicaid notice or fair hearing policy or operational requirements for states. |

1. Although this rule impacts multiple CMS programs, the analysis in this document includes primarily information regarding state Medicaid (42 CFR Parts 431, 435, 438, and 440) and CHIP (42 CFR Part 457) programs. In addition, given that dual eligible special needs plans (D–SNP) plans are a type of Medicare Advantage (MA) plans, changes to 42 CFR Part 422 are also included in this document. [↑](#footnote-ref-2)