

Policy Update

CMS Releases Advancing Interoperability and Improving Prior Authorization Processes Final Rule

Summary

On January 17, 2024, the Centers for Medicare & Medicaid Services (CMS) released a final rule that will require certain payers to automate their prior authorization processes and implement application program interfaces (APIs) to improve the exchange of health information among payers, providers and patients. The rule outlines these new requirements, exceptions to the requirements and implementation deadlines. It also adds a new electronic prior authorization measure that clinicians and hospitals must report as part of the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Category and the Medicare Promoting Interoperability Program, respectively.

The final rule comes at a time when Congress has been active on prior authorization reform, including through legislation. This article compares the final rule with that legislation, highlights policies that are not included in the final rule and discusses next steps for prior authorization reform.

The final rule is available here.

A CMS fact sheet on the final rule is available here.

Key Takeaways

- Impacted Payers: Payers subject to the rule include Medicare Advantage (MA) and Medicare Advantage/ Medicare Part D (MA-PD) plans, state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans and CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges (FFEs).
- Prior Authorization: The rule outlines new timeframes for prior authorization decisions, although some stakeholders had called for quicker turnaround times, especially for urgent requests. CMS also finalized that impacted payers must provide a specific reason for denied prior authorization decisions and publicly report certain prior authorization metrics on their website. These requirements are effective beginning in 2026.
- APIs: CMS finalized proposals to require impacted payers to implement and maintain APIs to improve
 patient access to data, to facilitate care coordination among providers and to support care continuity. The
 requirements for the Patient Access, Provider Access, Payer-to-Payer and Prior Authorization APIs must
 be met by January 1, 2027.
- Extensions, Exemptions and Exceptions: State Medicaid and CHIP FFS programs may apply for certain extensions or exemptions to the Provider Access, Payer-to-Payer and/or Prior Authorization API requirements. An exception process is also available to issuers applying for QHP certification that cannot satisfy the requirements for the Provider Access, Payer-to-Payer and Prior Authorization APIs.



- **New Provider Requirements:** CMS created new electronic prior authorization measures for MIPS and the Medicare Promoting Interoperability Program effective for the 2027 performance periods.
- **Timeline:** The rule's API requirements will take effect on **January 1, 2027**, which is a one-year implementation delay from what was proposed. Prior authorization process changes and timeframe requirements begin in **2026**. Impacted payers must report required prior authorization metrics by March 31, 2026.
- **Provider Savings:** CMS estimates that this rule will result in at least \$16 billion in savings, primarily for providers, over 10 years.
- **Not Addressed:** The requirements in the rule explicitly exclude prescription drugs and do not apply to employer-sponsored insurance plans or Medicare FFS. CMS did not address payers' use of algorithms or artificial intelligence (AI) to make prior authorization decisions.
- Congressional Interest in Prior Authorization: Legislation that would apply only to MA plans, the
 Improving Seniors' Timely Access to Care Act (H.R. 3173/S. 3018 in the 117th Congress), proposed
 faster required approval timelines for prior authorization requests than the timelines in CMS's final rule.
 The legislation stalled in the last session of Congress because of its cost. CMS's final rule may bring the
 legislation's cost down or might spur lawmakers to further amend the bill. Beyond legislation, Congress is
 using hearings, investigations and letters to highlight perceived problems with prior authorization
 practices.

Improving Prior Authorization Processes

Key Takeaway: The rule outlines new timeframes for prior authorization decisions, although some stakeholders had called for quicker turnaround times, especially for urgent requests. CMS also finalized a requirement that impacted payers provide a specific reason for denied prior authorization decisions and publicly report certain prior authorization metrics on their website. These requirements are effective beginning in 2026.

The final rule makes changes to prior authorization processes across impacted payers that are effective beginning in 2026. Impacted payers include MA and MA-PD plans, state Medicaid and CHIP FFS programs, Medicaid managed care plans and CHIP managed care entities, and QHP issuers on the FFEs.

Timeframes for the Prior Authorization Process

Beginning January 1, 2026, the final rule requires impacted payers, except for QHP issuers on the FFEs, to respond to prior authorization requests within certain timeframes. Impacted payers would have 72 hours to respond to expedited requests, unless a shorter minimum timeframe is established under applicable state law, and seven calendar days for standard requests, with the possibility of an extension of up to 14 days in certain circumstances.

CMS acknowledged that some payers affected by the final rule have different requirements for prior authorization decision notice and appeal timeframes, and the final rule aligns the prior authorization decision timeframes across those payers, except for QHPs on the FFEs.

With respect to QHP issuers on the FFEs, CMS explained that it did not change timeframes for prior authorization processes because existing regulations applicable to individual health insurance issuers require issuers to meet minimum internal claims and appeals standards. CMS explained that QHP issuers on the FFEs are currently required to provide notification of a plan's benefit determination within 15 days for standard authorization decisions and within 72 hours for expedited requests, which CMS stated is consistent with the requirements for other payers affected by this final rule.



Requirements for the Prior Authorization Process

The rule finalizes certain general requirements for the prior authorization process. Beginning in 2026, impacted payers must provide a specific reason for denied prior authorization decisions. When denial information is sent to a provider by any communication method, including existing notices, the content of a denial should be sufficiently specific to enable a provider to understand why a prior authorization has been denied and what actions must be taken to resubmit or appeal.

Reporting Requirements

CMS also finalized a requirement for impacted payers to report certain aggregated metrics about prior authorization by posting them on the payer's website. Impacted payers must make reports available annually on all of the following:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the review timeframe was extended and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan or issuer, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan or issuer, for expedited prior authorizations, aggregated for all items and services.

After considering commenters' feedback suggesting more granularity in MA prior authorization data reporting, CMS finalized that **MA organizations must report data at the contract level** rather than the organization level as proposed. CMS finalized, as proposed, that state Medicaid and CHIP FFS programs will report at the state level, Medicaid managed care plans and CHIP managed care entities will report at the plan level, and QHP issuers on the FFEs will report at the issuer level. CMS signaled its willingness to explore further reporting requirements in future rulemaking, such as service-specific and demographic data, publication of the data on a central website for comparative purposes, and requirements on the format of the reporting to make the data easy to understand and accessible.

By March 31, 2026, MA organizations at the contract level, state Medicaid and CHIP FFS programs at the state level, Medicaid managed care plans and CHIP managed care entities at the plan level, and QHP issuers on the FFEs at the issuer level must post the required metrics on their websites annually.



APIs

Key Takeaway: CMS finalized proposals to require impacted payers to implement and maintain APIs to improve patient access to data, to facilitate care coordination among providers and to support care continuity. The requirements for the Patient Access, Provider Access, Payer-to-Payer and Prior Authorization APIs must be implemented by January 1, 2027, a year later than CMS originally proposed.

Prior Authorization API

The final rule requires impacted payers to implement and maintain a Prior Authorization API.

Under the rule, the Prior Authorization API must:

- Be populated with the payer's list of covered items and services (excluding drugs) that require prior authorization;
- Be able to identify all documentation required for approval of any items or services that require prior authorization;
- Support a HIPAA-compliant prior authorization request and response; and
- Communicate whether the payer approves the prior authorization request (and the date or circumstance under which the authorization ends), denies the prior authorization request (with a specific reason) or requests more information.

The rule requires that the Prior Authorization API meet certain technical standards: HL7 FHIR Release 4.0.1, US Core IG STU 3.1.1 and SMART App Launch IG Release 1.0.0.

The compliance date for the Prior Authorization API policy is January 1, 2027.

Patient Access API

In CMS's Interoperability and Patient Access Final Rule, the agency required impacted payers to implement an HL7® FHIR® Patient Access API to easily access claims and encounter information, along with clinical data, including laboratory results, provider remittances and patient cost-sharing pertaining to such claims, if maintained by the impacted payer.

In the current final rule, CMS requires impacted payers to include information about certain prior authorizations in the data that are available through the Patient Access API, including the specific reason for a denial. CMS modified its proposal and will not require payers to share the quantity of items or services used under a prior authorization or unstructured documentation related to a prior authorization. Impacted payers are required to make prior authorization information available via the Patient Access API within one business day of receiving a request and must update prior authorization information within one business day of any status change. Information must remain available for as long as the authorization is active and at least one year after the last status change. CMS also modified its proposal that MA organizations must report Patient Access API metrics at the organizational level and finalized that they be reported at the contract level.

The rule finalized CMS's proposal to ensure that the data content requirement is automatically updated as the Office of the National Coordinator for Health Information Technology (ONC) adopts new versions of the United States Core Data for Interoperability (USCDI). CMS noted that impacted payers are required to make available generally the same information about prior authorization requests and decisions via the Provider Access and Payer-to-Payer APIs as well, so that prior authorization data can be available to all relevant parties.

As with the Prior Authorization API, CMS requires impacted payers to implement and maintain these changes by January 1, 2027, one year later than proposed. The specific compliance dates are 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; and for plan years beginning on or after January 1, 2027, for QHP issuers on the FFEs.

CMS will also require impacted payers to begin annually reporting to CMS in 2026 on certain metrics about patient data requests made via the Patient Access API, in the form of aggregated, de-identified data.

Provider Access API

The final rule requires impacted payers to implement and maintain a Provider Access API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient. The API must be consistent with the technical standards finalized in the Interoperability and Patient Access Final Rule, including the HL7® FHIR® Release 4.0.1 standard. The current rule specifies that providers can use the Provider Access API to access current patient data from payers, including adjudicated claims and encounter data (excluding provider remittances and patient cost-sharing information), all data classes and data elements included in the USCDI, and prior authorization information. CMS finalized its opt-out framework, allowing patients or their representatives to opt out of data sharing under the Provider Access API policy at any time. Impacted payers also will be required to develop plain language resources about the Provider Access API for patients and providers.

CMS specified that the Patient Access API and the Provider Access API differ as to how and why the end user will access the data. For the Patient Access API, the patient requests access to their own data through a health app for their own reference and use, whereas for the Provider Access API, the agency expects that a provider will request and receive access to the patient's information through their electronic health record (EHR), practice management system or other technology for treatment purposes.

Like the other APIs, the compliance date for the Provider Access API policy is January 1, 2027.

Payer-to-Payer API

The final rule requires impacted payers to implement and maintain a Payer-to-Payer API to exchange patient data when a patient moves between payers, to ensure continued access to health data and support continuity of care between payers. The final rule specifies that the payer-to-payer data exchange will include adjudicated claims and encounter data (excluding provider remittances and patient cost-sharing information), all data classes and data elements included in the USCDI, and certain information about the patient's prior authorizations.

CMS will require impacted payers to request data from a patient's previous payer, with the patient's opt-in permission, no later than one week from the start of coverage or at the patient's request. Impacted payers will then be required to integrate any data they receive in response to that request into the patient's record. Payers will be required to exchange five years of patient data (as opposed to the entire patient health record). CMS noted that five years of data is sufficient to support care continuity and continuation of prior authorizations as necessary, and maintains patient access to their most recent data without significant burden to payers.

The agency noted that the Payer-to-Payer API utilizes standards and technology similar to that of the Patient Access API, and that the degree of overlap between the requirements for the Patient Access API and the Provider Access API should ease the development and implementation of the Payer-to-Payer API. CMS acknowledged that one operational difference between the Patient Access API and the Payer-to-Payer API is that payers may find it more efficient to share data for multiple patients at a time.

Impacted payers that are previous or concurrent payers will be required to respond to a current payer's request, if specified conditions are met, within one business day of receiving the request. Impacted payers (except for Medicaid managed care plans and CHIP managed care entities) also must provide patients with educational resources about the Payer-to-Payer API in plain language.



The compliance date for the Payer-to-Payer API policy is January 1, 2027.

Extensions, Exemptions and Exceptions

Key Takeaway: State Medicaid and CHIP FFS programs may apply for certain extensions or exemptions to the Provider Access, Payer-to-Payer and Prior Authorization API requirements. An exception process is also available to issuers applying for QHP certification that cannot satisfy the requirements for the Provider Access, Payer-to-Payer and Prior Authorization APIs.

CMS recognizes that state Medicaid and CHIP FFS agencies may face unique financing and operational circumstances that do not apply to other impacted payers. For example, some states need legislative approval to initiate a public procurement process to secure contractors for API development. Therefore, CMS will allow state Medicaid and CHIP FFS programs to apply for extensions or exemptions to the Provider Access, Payer-to-Payer and/or Prior Authorization API requirements.

States may request a one-time, one-year written **extension**. The extension request must include the following:

- A narrative justification describing the specific reasons why the state cannot satisfy the requirement(s) by the compliance dates, and why those reasons result from circumstances that are unique to the agency operating the Medicaid and/or CHIP FFS program.
- A report on completed and ongoing state activities that evidence a good faith effort toward compliance.
- A comprehensive plan to meet the requirements no later than one year after the compliance date.

State Medicaid and CHIP FFS programs also may apply for an **exemption** from the Provider Access, Payer-to-Payer and/or Prior Authorization API requirements when at least 90% of the state's Medicaid beneficiaries are enrolled in Medicaid managed care organizations (MCOs) or when at least 90% of the state's separate CHIP beneficiaries are enrolled in CHIP MCOs. However, the requirements for the Payer-to-Payer API to obtain beneficiaries' permission, provide educational resources at the time of requesting permission and identify patients' previous/concurrent payers, including for beneficiaries covered under managed care, are not eligible for the exemption. A state's exemption request must include documentation showing that the state meets the threshold criterion based on enrollment data and a plan to ensure that providers have efficient electronic access to the same information through other means while the exemption is in effect.

Under the final rule, an exemption will expire if, based on the three previous years of available enrollment data, the state's MCO enrollment for two of the previous three years is below 90%, or if CMS approves a state plan amendment, waiver or waiver amendment that would significantly reduce the percentage of beneficiaries enrolled in managed care and the anticipated shift in enrollment is confirmed by the first available finalized enrollment data.

CMS clarified that for states with Medicaid expansion CHIPs, the requirements for Medicaid will apply to those programs rather than the provisions for separate CHIPs.

CMS also finalized an **exception** process to the Provider Access, Payer-to-Payer and Prior Authorization APIs for issuers applying for QHP certification that cannot satisfy the requirements. The issuer must include, as part of its QHP application, a narrative justification describing the reasons why the issuer cannot reasonably satisfy the requirements for the applicable plan year, the impact of noncompliance upon providers and enrollees, the current or proposed means of providing health information to providers or other payers, and solutions and a timeline to achieve compliance with the requirements.



Electronic Prior Authorization Measures for MIPS Promoting Interoperability Performance Category and Medicare Promoting Interoperability Program

Key Takeaway: CMS created new electronic prior authorization measures for MIPS and the Medicare Promoting Interoperability Program effective for the 2027 performance periods.

CMS believes that the Prior Authorization API will only be successful in reducing administrative burden, improving efficiency and ensuring patients promptly receive necessary medical services if providers also successfully complete prior authorization requests. CMS therefore proposed and finalized new measures related to electronic prior authorization and the Prior Authorization API for MIPS eligible clinicians under the MIPS Promoting Interoperability performance category and for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program. The new measures, both titled Electronic Prior Authorization, will be included in the Health Information Exchange objectives for both programs. While CMS proposed adding the new Electronic Prior Authorization measures to MIPS and the Medicare Promoting Interoperability Program in the 2026 performance periods, CMS finalized an effective date of the 2027 performance periods to provide more time to adjust to the new electronic prior authorization workflow using the Prior Authorization API.

Although CMS originally proposed to have a numerator and denominator associated with the measures, CMS finalized the measures as an **attestation** (**yes/no**). MIPS eligible clinicians and eligible hospitals and CAHs must report a "yes" to the attestation or claim an exclusion to meet the reporting requirement. If they report "no," they will not be considered a meaningful EHR user and will fail to meet minimum program reporting requirements. For MIPS, such a failure would result in a score of zero for the MIPS Promoting Interoperability performance category. A MIPS eligible clinician's score in the Promoting Interoperability performance category is generally worth 25% of their total final score for MIPS. For hospitals and CAHs, failure to meet the minimum program reporting requirements would result in a downward payment adjustment (unless the eligible hospital or CAH receives a hardship exception).

CMS also finalized its proposal regarding reporting exclusions for this measure. MIPS eligible clinicians and eligible hospitals or CAHs that do not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period or EHR reporting period can claim an exclusion for the Electronic Prior Authorization measure. MIPS eligible clinicians and eligible hospitals or CAHs that only order medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer a Prior Authorization API also can claim an exclusion.

Interoperability Standards for APIs

Key Takeaway: CMS requires certain standards for the Patient Access, Provider Access, Provider Directory, Payer-to-Payer and Prior Authorization APIs.

CMS will require payers to use specifications that are listed in <u>Table H3 of the rule</u> for the Patient Access, Provider Access, Provider Directory, Payer-to-Payer and Prior Authorization APIs. CMS will allow impacted payers to use updated standards, specifications or implementation guides (IGs) for each of these APIs under the following conditions:

- The updated version of the standard is required by other applicable law; or
- The updated version of the standard is not prohibited under other applicable law, the National Coordinator has approved the updated version for use in the ONC Health IT Certification Program, and the updated version does not disrupt an end user's ability to access the data



required to be available through the API.

Impacts of Regulation

Key Takeaway: CMS estimates that this rule will result in at least \$16 billion in provider savings over 10 years.

CMS projects that the rule will reduce the total burden across all providers by at least 220 million hours over 10 years, resulting in a total cost savings to providers of at least \$16 billion over 10 years. CMS estimates that it will take the combined 365 impacted payers more than six million hours to comply with the requirements annually, costing them \$182 million in years one and two of implementation, \$199 million in year three, and \$142 million annually going forward. CMS estimates that clinicians, hospitals and CAHs will have minimal burden in attesting to the new Electronic Prior Authorization measures in MIPS and the Medicare Promoting Interoperability Program.

Entity	Number of respondents	Estimated annual burden (hours)	1st year cost (in millions)	2nd year cost (in millions)	3rd year cost (in millions)	Subsequent annual cost (in millions)
Payers	365	6,895,945	\$182	\$182	\$199	\$142
Clinicians	54,770	456				\$0.02
Hospitals and CAHs	4,500	37				\$0.00
All payers, MIPS eligible clinicians, and eligible hospitals and CAHs combined	59,635	6,896,438	\$182	\$182	\$199	\$142

What the Rule Doesn't Address

Key Takeaway: The requirements in the rule do not apply to prescription drugs, employersponsored insurance plans or Medicare FFS. CMS did not address payers' use of algorithms or Al to make prior authorization decisions.

Prescription Drugs

CMS was explicit in this rule that prescription drugs are excluded from the Prior Authorization API and prior authorization process requirements. CMS noted that state Medicaid programs and the MA program have timing requirements for prior authorizations for coverage of drugs that are similar to the requirements finalized in this rule for coverage of medical items and services. For example, MA plans are required to respond to expedited requests for Part B drugs within 24 hours and to non-expedited drugs as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. Similar timelines apply to MA-PD plans that cover Part D drugs. Under Medicaid (both FFS and managed care), if a state requires prior authorizations for covered outpatient drugs, a response must be provided within 24 hours of the request for prior authorization, although CMS acknowledged that certain drugs, including cancer drugs, do not meet the definition of "covered outpatient drugs." Citing overwhelming stakeholder comments, CMS expressed openness to developing future policy options for regulation of prior authorization requirements around prescription drugs.

Employer-Sponsored Insurance Plans

The requirements CMS finalized in this rule generally apply across MA organizations, state Medicaid FFS programs, state CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities and QHP issuers on the FFEs. However, the policies do not apply across all health insurance issuers and



group health plans subject to the Public Health Service Act, most notably employer-sponsored plans and other group health insurance. CMS acknowledged commenters' concerns about the inapplicability of the rules to employer-sponsored plans in particular and the 150 million Americans covered by such plans. CMS explained, however, that the finalized requirements fall under its authority to regulate only issuers in the exchanges that CMS operates. The agency encourages plans not governed by the final rule to voluntarily meet the rule's requirements.

Medicare Fee-for-Service

The requirements in this rule also do not directly pertain to Medicare FFS. However, CMS stated its intention for the Medicare FFS program to be a market leader on data exchange, including through the Provider Access, Payer-to-Payer and Prior Authorization APIs. While the proposed rule solicited comments on how the policies could apply to Medicare FFS, CMS did not make any policy proposals to do so and did not include any such policies in this final rule. CMS stated that it will consider comments on application of the final policies to Medicare FFS as it plans its "roadmap for implementation."

Artificial Intelligence

In this rule, CMS did not directly address the use of algorithms or AI in prior authorization, even though stakeholders urged CMS to do so. CMS stated that how prior authorization decisions are made (such as by using AI, statistical methods, requirements for clinical decisions or other algorithms) is outside the scope of this specific rulemaking. CMS clarified, however, that prior authorization decisions involving AI or other algorithmic systems must still comply with applicable requirements, including requirements around clinical decision-making and the finalized policy requiring communication of the specific reason for denial.

Congressional Interest in Prior Authorization

Key Takeaway: Legislation that would apply only to MA plans proposed faster approval timelines for prior authorization requests than the timeline requirements in CMS's final rule. The bill stalled in the last session of Congress because of its cost. Finalization of CMS's rule may bring the legislation's cost down or could spur lawmakers to further amend the bill. Beyond legislation, Congress is using hearings, investigations and letters to highlight perceived problems with prior authorization practices.

In parallel with CMS's efforts, lawmakers on Capitol Hill have been pursuing various inquiries into, and reforms of, insurers' prior authorization processes.

The Improving Seniors' Timely Access to Care Act (H.R. 3173/S. 3018 in the 117th Congress), led by Reps. Mike Kelly (R-PA), Suzan DelBene (D-WA), Larry Bucshon (R-IN) and Ami Bera (D-CA) in the US House of Representatives and Sens. Doc Marshall (R-KS), Kyrsten Sinema (I-AZ), John Thune (R-SD) and Sherrod Brown (D-OH) in the US Senate, has been Capitol Hill's primary legislative effort on prior authorization. In the 117th Congress, the bill had 326 cosponsors in the House and 52 cosponsors in the Senate. It would require MA plans to establish an electronic prior authorization process to streamline approvals and denials, provide real-time prior authorization for items and services that are routinely approved, and publicly report data on prior authorization metrics.

The bill unanimously passed the House last Congress, and in September 2022 it was endorsed by more than 500 healthcare organizations. However, a \$16 billion score from the Congressional Budget Office (CBO)—higher than many lawmakers and stakeholders anticipated—stalled further congressional consideration. In its estimate, CBO explained that prior authorization is a utilization management tool and that by placing additional requirements on plans that use prior authorization, the legislation would result in a greater use of services, in CBO's estimation. In turn, MA plans would increase their bids to include the cost of these additional services, which would result in higher payments to plans.

In the current Congress, the House Committee on Ways and Means included the Improving Seniors'



Timely Access to Care Act in its <u>Health Care Price Transparency Act of 2023</u>, which it favorably reported out of committee in July 2023. But in this session of Congress, the sponsors delayed introduction pending release of CMS's final rule. It is widely expected that the bill will be reintroduced shortly.

Below, we crosswalk the requirements of the Interoperability and Prior Authorization Final Rule with the requirements that would apply under the current version of the Improving Seniors' Timely Access to Care Act:

Turner of plans offsets d	Regulation: Interoperability and Prior Authorization Final Rule	Legislation: Improving Seniors' Timely Access to Care Act Medicare MA		
Types of plans affected	Medicare MA, Medicaid FFS, Medicaid MCO, CHIP FFS, CHIP Managed Care, QHP issuers on the FFEs	Medicare MA		
Items and services included/excluded	Medical items and services, other than any drugs covered by any impacted payer	Any item or service for which benefits are available under an MA plan, other than a covered part D drug		
	Existing prior authorization requirements for MA and MA-PD plans around Part B and Part D drugs, as well as Medicaid state requirements around prior authorization for covered outpatient drugs (which excludes cancer drugs), continue to apply.			
Require payers to build and maintain an electronic prior authorization process?	Yes	Yes		
Require payers to include a specific reason when they deny a prior authorization request?	Yes	Yes		
Require real-time prior authorization decisions for certain items and services?	No	Yes		
Establish time limits for payers to send prior authorization decisions?	Yes, within 72 hours for urgent requests and seven calendar days for non-urgent requests	Yes, if not real-time, within 24 hours for urgent requests and 72 hours for non-urgent requests		
Require payers to publicly report certain prior authorization metrics on their websites?	Yes	Yes		

Given their leadership on prior authorization—and the impediments to passing the Improving Seniors' Timely Access to Care Act—the bill's congressional sponsors have taken a keen interest in CMS rulemaking on the topic. When CMS issued the Interoperability and Prior Authorization Proposed Rule in



December 2022, sponsors of the Improving Seniors' Timely Access to Care Act <u>commended</u> the rulemaking as bringing their bill one step closer to becoming law. In June 2023, the bill's sponsors issued a <u>letter</u> signed by 233 members of the House and 61 senators (majorities in both bodies) calling on CMS to promptly finalize and implement its proposals and expand them to more closely align with provisions of the Improving Seniors' Timely Access to Care Act. In particular, lawmakers urged CMS to establish a mechanism for real-time prior authorization decisions for routinely approved items and services, require plans to respond to prior authorization requests within 24 hours for urgently needed care and require detailed transparency metrics. Upon release of the Interoperability and Prior Authorization Final Rule, lawmakers <u>lauded</u> the rule while noting that CMS could have gone further. They called on Congress to pass the Improving Seniors' Timely Access to Care Act to cement the rule's requirements.

It remains to be seen whether CMS's final rule will spur further congressional consideration of the Improving Seniors' Timely Access to Care Act in this Congress. The legislation's cost has been an impediment to passage, but finalization of the Interoperability and Prior Authorization Rule could provide some relief since CBO estimates typically account for policy changes that have already been made administratively. It is widely expected that the bill's sponsors will reintroduce the legislation in short order and work with CBO on scoring in light of the CMS final regulations.

Beyond the Improving Seniors' Timely Access to Care Act, Members of Congress have used hearings, investigations and letters to CMS to raise concerns around various aspects of plans' prior authorization practices.

In May 2023, the Senate Homeland Security and Governmental Affairs Permanent Subcommittee on Investigations held a hearing, "Examining Health Care Denials and Delays in Medicare Advantage." At the hearing, the US Department of Health and Human Services (HHS) Inspector General testified about its April 2022 report that found high rates of prior authorization denials by some MA organizations.

In September 2023, Senate Finance Committee Chair Ron Wyden (D-OR) and House Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-NJ) <u>launched an investigation</u> into the prior authorization practices of Medicaid managed care plans. They sent letters to the seven largest Medicaid managed care providers requesting that they submit information on the rate of appeals and denials in their plans, and information on any Al algorithms used in the prior authorization process. As justification for this inquiry, lawmakers cited a July 2023 HHS Inspector General <u>report</u> that found high rates of prior authorization denials by some Medicaid managed care plans.

In November 2023, House Democrats sent a <u>letter</u> to CMS expressing concern that its regulatory efforts to date had not addressed plans' use of AI to guide prior authorization decisions. These lawmakers urged CMS to prohibit outright the use of AI in prior authorization.

Next Steps on Prior Authorization Policy

Even within the Interoperability and Prior Authorization Final Rule, CMS hinted at areas it may address in future rulemaking. With respect to drugs, for example, CMS said that based on the overwhelming number of comments urging the agency to reconsider its exclusion of drugs from the final rule's policies, it would consider options for future rulemaking to address improvements to payers' prior authorization processes for drugs.

On reporting requirements, CMS said it would assess whether to collect more detailed metrics than it finalized in the rule. CMS also signaled that it could require reporting on prior authorization metrics at a more granular level. In this rule, CMS already finalized a more granular level of required reporting for MA organizations than it proposed (the contract level rather than the organization level) but said it might consider in the future whether plan-level reporting would be appropriate.



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While CMS characterized plans' methods for making prior authorization decisions as out of scope for this rulemaking, progress toward regulating Al tools is anticipated with the implementation of the president's <u>executive order</u>, and the use of Al for prior authorization could be addressed in that context. Congress is also ramping up its oversight of Al in healthcare by holding hearings in the <u>Senate Committee on Health</u>, <u>Education</u>, <u>Labor</u>, <u>and Pensions</u>; the <u>House Energy and Commerce Health Subcommittee</u>; and the <u>full House Energy and Commerce Committee</u>.

Finally, payers not impacted by the Interoperability and Prior Authorization Final Rule (in particular, payers of employer-sponsored health insurance plans) could be subject to regulations or legislation to address their prior authorization practices.

In 2024 and beyond, <u>expect</u> both regulators and Congress to continue prior authorization oversight and reform efforts.

For more information, contact Leigh Feldman, Jeffrey Davis or Erica Stocker

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