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CMS Publishes Interoperability and Prior Authorization Final Rule: What It Will Mean for Patient Access

Prior authorization – the requirement that a provider justify the clinical need for a particular service before a plan will cover it – has long been a contentious topic. Plans argue the practice is needed to prevent inappropriate use of services and to save the health system money, while providers and patients argue that prior authorization is an onerous and often arbitrary barrier to necessary care and treatment. Over the past several years, advocates have been pushing both state and federal regulators to better regulate the prior authorization process for public and private payers, including by limiting the types of services prior authorization can be applied to, requiring more transparency regarding prior authorization decisions, and requiring decisions to be made within certain timelines.

On January 17, 2024, in an earlier than forecasted move, the Biden Administration issued a sweeping [final rule](#) that, among a slew of other data interoperability provisions, added new requirements for impacted payers to follow when it comes to prior authorization for items and services other than prescription drugs. The rule applies to Medicare Advantage plans, state Medicaid and Children’s Health Insurance Program (CHIP) programs, Medicaid and CHIP managed care plans, and individual and small group plans available on the Federally Facilitated Exchanges (FFE). The rule is a big step for increased federal scrutiny over payer practices surrounding prior authorization. The following includes a summary of the rule’s major provisions and when they go into effect.

What Is Prior Authorization?

Prior authorization is a form of utilization management, which is an umbrella term for techniques that insurance companies use to manage health care costs through case-by-case assessments of whether specific types of care are appropriate for a given patient. A prior authorization requirement is when a plan requires a provider to submit a justification for a patient’s proposed treatment or service before the patient may access that treatment or service. The plan then decides whether the treatment or service meets the plan’s criteria for coverage or not.

[Data from Kaiser Family Foundation](#) indicates that challenges related to prior authorization processes can lead to patients delaying or foregoing care recommended by their providers. Providers can also spend [hours of administrative time](#) filling out paperwork justifying the clinical need for a particular service, which contributes to [provider burnout](#). Information about the criteria a plan uses to approve a prior authorization request is often difficult to find or opaque, which leaves providers and patients guessing as to the circumstances under

which the plan will grant access to a particular service. The back-and-forth with insurers on approving a prior authorization request often involves multiple requests and appeals and causes delays in access to necessary care and treatment.

The New Rule

The new rule finalized on January 17 includes two main tactics designed to ease administrative burdens and patient access barriers related to prior authorization in affected insurance plans (Medicare Advantage plans, state Medicaid and CHIP fee-for-services programs, Medicaid and CHIP managed care plans, and individual and small group plans available on FFEs).

1) *Improving Access to Health Data*

The final rule adds several requirements aimed at making it easier for patients, providers, and payers to access health information through new API requirements. An API – or application program interface – is a set of programming code that allows two applications to talk to each other. In the context of health data, APIs allow datasets to be displayed in an accessible form in real time (e.g., many plans use an API to allow beneficiaries to search provider networks). [Previous interoperability rules](#) had already required payers to develop and use APIs to make data more accessible to patients and providers. The new rule released last week includes additional requirements for payers regarding their APIs:

- **Patient Access API:** Previous interoperability rules had required payers to make patient data more easily available via third-party apps through Patient Access API requirements. The new rule adds to those requirements by requiring payers to add information about prior authorizations (excluding those for drugs) to the data available via that Patient Access API (in addition to the Prior Authorization API mechanism discussed below).
- **Provider Access API:** Payers must make individual claims and encounter data and specified prior authorization information (excluding those for drugs) available via a Provider Access API.
- **Payer-to-Payer API:** Payers must implement and maintain a Payer-to-Payer API to make available claims and encounter data available to other payers. This will allow for more continuity of care as individuals transition across payers (e.g., a payer can use a patient's data to determine whether they have a chronic condition and are on a treatment regimen that needs to be maintained).
- **Prior Authorization API:** Payers must provide prior authorization information to patients and providers through a new Prior Authorization API, which includes information on covered items and services and what documentation is required for prior authorization request. The API must allow a provider to submit a prior authorization request and must provide information as to whether the request has been approved or denied. If the request was denied, the API must provide the specific denial reason. The API must also make a more limited set of data on prior authorization available to other payers to help ensure continuity of care and treatment when patients transition to a new plan.

These requirements go into effect in January 2027. The final rule also applies more uniform interoperability technical standards to each data API, ensuring that payers use appropriate data security and exchange policies and procedures to safeguard patient information while supporting streamlined exchange of data. Noting that

some patients may wish to limit access to their sensitive health information, the rule also includes opt out provisions to limit the data that providers and payers may access via the Provider Access API and the Payer-to-Payer API.

2) *New Procedural Requirements for Prior Authorizations*

The final rule also adds several procedural rules aimed at increasing transparency, timeliness, and fairness in prior authorization processes. These rules apply generally to prior authorization requests for items and services other than prescription drugs, which are not included in the new rule.

Transparency

The rule requires payers to notify providers when a prior authorization request is denied, including giving specific reasons for the denial. Payers must also provide health plan enrollees with information regarding the plan's prior authorization policies, including items and service subject to prior authorization, the timeframes in which decisions about prior authorization will be made, the criteria by which the payer will make a decision regarding prior authorization, and how a beneficiary or enrollee can appeal a prior authorization decision. Much of this information should be available via the Prior Authorization API discussed above. The rule also requires payers to publicly report aggregate data on certain prior authorization metrics, which may help guide future regulatory action and enforcement.

Decision Timelines

The final rule includes specific timelines for when standard and expedited prior authorization requests must be decided by the payer. The rule makes most of the prior authorization decision timelines uniform across payers. These decision timelines go into effect in 2026.

Payer	Expedited PA Decision Timeline	Standard PA Decision Timeline
Medicare Advantage	No later than 72 hours after receiving request	No later than 7 calendar days after receiving the request
Medicaid managed care plans*	No later than 72 hours after receiving the request	No later than 7 calendar days after receiving the request
Medicaid FFS*	No later than 72 hours after receiving the request	No later than 7 calendar days after receiving the request
QHP issuers on FFEs	No later than 72 hours after receiving the request	A reasonable period of time appropriate to the medical circumstances, but not later than 15 days after receiving the request

*State law may set shorter timeframes for Medicaid prior authorization decisions

Medicaid Fair Hearing Rights

The rule does not change existing protections for Medicaid beneficiaries to appeal adverse coverage decisions. The rule clarifies that existing Medicaid beneficiary notice and fair hearing rights apply to prior authorization decisions.

What's Left Out of the Rule and What's Next?

Notably, the final rule does not include prior authorization standards for prescription drugs. CMS received many comments asking the agency to include prescription drugs in its rulemaking given the many access challenges opaque and arbitrary prior authorization policies have for consumers. CMS noted these comments and indicated that specific rulemaking on prior authorization for prescription drugs would be forthcoming. Because prior authorization requirements are often applied to prescription drugs, advocates should continue to push for standards in this area.

The new rule represents a broader federal commitment to both easing access to and sharing of healthcare data and better regulating plan processes when it comes to coverage decisions and utilization management. Future rulemaking is likely on this issue, particularly as payers move toward more automated mechanisms for utilization management and coverage decisions via artificial intelligence.

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