Issue Brief: Federal changes to prior authorization rules and their impact on state legislative efforts

Recent changes to federal prior authorization rules for certain plans may impact or influence state reform efforts. It will be important for physicians, medical societies, and other physician and patient advocates to help educate state policymakers as to how these changes impact proposed state legislation and where it is critical that additional state legislative and regulatory changes are made to protect patients, physicians and health care resources.

Centers for Medicare & Medicaid Services (CMS) Prior Authorization and Interoperability final rule

On January 17, 2024, CMS released the Prior Authorization and Interoperability final rule. The final rule makes important reforms in prior authorization programs for medical services and supports increased data exchange between health plans, health care professionals, and patients. Depending on the provision, these requirements take effect in 2026 and 2027 and apply to health plans regulated by the federal government. The rule's provisions are specific in scope, both in terms of treatments addressed and types of plans to which they apply.

Impacted payers

The rule makes changes to prior authorization requirements under Medicare Advantage, Medicaid, Medicaid Managed Care, Children's Health Insurance Program (CHIP), CHIP managed care, and Qualified Health Plans (QHPs) on federally facilitated exchanges (FFEs); however, not all changes in the rule apply to all programs.

CMS indicates that it has already or plans to implement the technologies required under the rule for Medicare fee-for-service (FFS). In addition, CMS strongly encourages insurers to implement the rule's requirements across commercial and employer-sponsored plans.

No changes to prior authorization rules for prescription drugs

All outpatient drugs—whether administered in a physician's office or by the patient at home—are outside the scope of the rule. CMS indicates that drugs were excluded from consideration due to differences in the electronic standards used for administrative processing. In addition, CMS notes that processing timeframe requirements already exist for Medicare Part B and Medicare Part D drugs (24 hours for urgent prior authorization requests and 72 for standard requests).

Requirements on payers and health plans

- ***Specific denial reasons:*** All impacted payers and plans must provide a specific reason for denying a prior authorization request. Examples of what constitutes a "specific reason" include reference to the relevant plan provision, coverage criteria citation, narrative explanation, or an indication that the submitted documentation did not support the request. Such information should also communicate the action needed to

obtain coverage, whether that be submitting an appeal or additional information or selecting an alternative treatment option identified by the plan. Plans must comply with these requirements by January 1, 2026.

- ***Response times:*** Payers and plans are required to send prior authorizations decisions no later than 72 hours for urgent (i.e., "expedited") requests and no later than 7 calendar days for non-urgent (i.e., "standard") requests. Plans may be able to extend the processing timeline in unique circumstances (e.g., when more information is required to determine coverage) and must follow any applicable shorter state deadlines. Plans must comply with these requirements by January 1, 2026. QHPs on FFEs are not required to meet timeframes requirements. Additionally, previously existing regulations require that health plans respond in 24 hours for urgent requests for Medicare Part B prescription drugs.

- ***Public reporting:*** Payers and plans must post program metrics on their websites, to include:

    - A list of all items and services that require prior authorization;
    - The percentage of urgent and non-urgent requests that were approved, denied, and approved after appeal;
    - The percentage of prior authorization requests for which the timeframe for review was extended; and
    - The average and median time that elapsed between the submission of a request and issuance of a decision by the payer for urgent and non-urgent requests.

  MA plans must report at the contract (vs. organization) level. Medicaid and CHIP managed care plans will report at the plan level, QHP issuers on the FFEs will report at the issuer level, and state Medicaid and CHIP programs will report at the state level. These data will be aggregated across all services; CMS notes that it may require more granular reporting for categories of items or services in the future. Impacted plans must post these data by March 31, 2026, with annual updates required thereafter.

- ***Automation:*** Payers are required to offer several application programming interfaces (APIs).[1] An API is defined in the rule as "a set of commands, functions, protocols, or tools published by one software developer ('A') that enables other software developers to create programs (applications) that can interact with A's software without needing to know the internal workings of A's software while maintaining data security and patient privacy (if properly implemented)." These API requirements are effective January 1, 2027:

    - *Prior authorization API:* Payers must implement and maintain an API what connects to a physician practice's electronic health record (EHR) and allows the physician to determine if a service being ordered requires prior authorization, the documentation requirements necessary for approval, and whether the request is approved, denied, or requires additional information before a determination can be made. CMS allows the flexibility for covered entities to implement an all-Fast Healthcare Interoperability Resources (FHIR)-based API that does not use the X12 278 standard as part of their API implementation. While physicians are not required to use the prior authorization API, they are "incented" to adopt this technology under a new Merit-based Incentive Payment System (MIPS) Promoting Interoperability requirement.

    - *Patient Access API:* Building on an existing requirement that payers implement an HL7® FHIR® Patient Access API to allow patients access to health care data for their own use with an app, the rule requires payers to supply data regarding prior authorization status, the date the request was approved/denied, the end date for the approval, the items/services approved, reasons for denial, and

[1] Recent CMS regulations propose to require certified EHR developers to provide the technology necessary for practices to use these prior authorization APIs.

structured administrative and clinical data submitted by the provider to support the PA request within one day of the patient's request or change of PA status. The final rule also requires impacted plans to begin reporting on usage of the Patient Access API to CMS annually, beginning March 31, 2026.

- *Provider Access API:* Payers must implement and maintain a Provider Access API to make patient data available to in-network physicians with whom the patient has a demonstrated treatment relationship. This API must include claims and encounter data (without provider remittances and enrollee cost-sharing information) and all data elements and classes in the United States Core Data for Interoperability (USCDI). It must also include prior authorization-related data (excluding drugs), including the same prior authorization information as the Patient Access API. Patients can opt out of making their data available to providers under these requirements.

2024 Medicare Advantage Final Rule

In April, 2023, CMS released the 2024 MA and Part D final rule. The final rule made meaningful changes to the prior authorization process under MA that generally took effect January 1, 2024. The prior authorization changes did *not* impact Medicare Part D, the Medicare prescription drug program.

New requirements on MA plans:

- ***Use of prior authorization***: MA plans may use prior authorization only to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, ensure an item or service is medically necessary based on specified standards, or ensure that the furnishing of supplemental benefits is clinically appropriate.

- ***Prohibition of retroactive denials:*** If the MA plan approved a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause or if there is reliable evidence of fraud or similar fault.

- ***Prior authorization approval duration:*** Approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation.

- ***Grace period when switching plans:*** MA plans may not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days. This includes enrollees new to a plan and enrollees new to Medicare.

- ***Qualifications of reviewers:*** If an MA plan expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA plan issues the decision.

- ***Same access as Medicare FFS***: MA beneficiaries must have access to the same items and services as they would under traditional Medicare. MA plans must use applicable Medicare statute, regulation, National Coverage Determinations (NCDs), or Local Coverage Determinations (LCDs) rather than internal or proprietary coverage criteria.

- ***Limitations on use of internal criteria:*** MA plans may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature only when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs, or LCDs.

- ***Limitations on restricting care setting or provider type:*** MA plans cannot deny care ordered by a contracted physician unless medical necessity criteria are not met, thereby restricting plans' ability to steer patients to providers or settings that may not be the most appropriate based on individual factors.

- ***Behavioral health emergencies exemption:*** The final rule clarifies that behavioral health services furnished as emergency services cannot be subject to prior authorization.

- ***Utilization management committee:*** MA plans that use utilization management (UM) policies, including prior authorization, must establish a UM Committee that is led by a plan's medical director and includes practicing physicians. Plans may not use UM policies and procedures unless they have been approved by the UM committee.

- ***Goldcarding programs:*** In the final rule, CMS encouraged MA plans to adopt goldcarding programs that exempt physicians with high prior authorization approval rates from such requirements.

Existing Rules for Medicare Part D, the Medicare prescription drug program

Although prescription drugs were largely excluded from the two most recent CMS rules on prior authorization programs, there are some existing prior authorization guardrails in place for Medicare Part D plans.

- ***Response times***: Part D plans are required to process urgent prior authorization requests in 24 hours and non-urgent requests in 72 hours.

- ***Automation***: Part D plans are required to support the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for electronic Prior Authorization (ePA) transactions, and prescribers are required to use that standard when performing ePA transactions.

Opportunities for state policymakers[2]

These federal rules will greatly improve the prior authorization process for many patients and physicians, but much more work is needed, including at the state level, to ensure broader relief from the problems associated with these onerous and harmful programs.

State legislators should look to align commercial payer requirements with many of the requirements in these rules, recognizing the absurdity of plan arguments against such requirements that suggest these reforms will cost money or are difficult to implement. State policymakers should also take the opportunity to build on many of these federal requirements, using them as a floor for changes, to ensure greater patient protections in their state, and to fill in many of the policy gaps that continue to exist.

Align state requirements with certain federal requirements

- ***Ensure continuity of care***: An overwhelming majority (89%) of physicians report that prior authorization interferes with continuity of care and 61% of physicians report that prior authorization at least sometimes destabilizes a patient whose condition was previously stabilized on a specific treatment plan.

[2] Data cited in this section can be found at 2024 AMA prior authorization physician survey

- *Repeat prior authorization*: Policymakers should track the 2024 MA final rule requirements and prohibit repeat prior authorizations, especially for those with chronic conditions, that delay care and undercut the stability of a patient's health.

- *Grace period when switching health plans*: As now required of MA plans under the 2024 final rule, state legislation should mandate at least a 90-day grace period for patients switching between plans to ensure continuity of care for patients receiving an active course of treatment.

- ***Prohibit retroactive denials***: Patients and physicians should be able to rely on an authorization as a commitment to coverage and payment of the corresponding claim. But unfortunately, plans often issue denials of care even after the care is preapproved. State legislation should prohibit retroactive denials when care has received prior authorization, aligning with MA plan requirements under the 2024 MA final rule.

- ***Automation***: Prior authorization leads to substantial administrative burdens for physicians, taking time away from direct patient care, costing practices money and significantly contributing to physician burnout. In fact, physician practices report completing an average of 39 prior authorizations per physician per week and spend 13 hours each week completing them. Automation, when combined with judicious use of the process and guardrails to protect patients, could help relieve the prior authorization burden and harm. However, physicians report phone as the most commonly used method, and only 23% of physicians report that their EHR offers electronic prior authorization for prescription medications, despite the standard transaction being available for many years. Significant progress has been made at the federal level to promote automation in the prior authorization process, and states are well-advised to mirror federal requirements in their legislative efforts.

    - *Medical services*: State policy should align with federal requirements under the CMS Prior Authorization and Interoperability final rule and require that health plans offer a FHIR-based API that connects with a practice's EHR and allows the physician to determine if a service being ordered requires prior authorization, the documentation requirements necessary for approval, and whether the request is approved, denied, or requires additional information before a determination can be made.

    - *Prescription drugs*: To automate the prescription drug prior authorization process, state legislation should require that plans are required to support the NCPDP SCRIPT standard ePA transactions, as currently required under Medicare Part D.

Build upon federal requirements in state policy

- ***Apply all prior authorization reforms to prescription drugs:*** Many of the recent federal changes disappointingly fail to address prescription drug prior authorization programs. However, rampant use of prior authorization on prescription drugs regularly threatens patients' health and wastes health care resources. For example, generic drugs are regularly subject to prior authorization requirements (over half of physicians report use of prior authorization on generics), and patients find themselves constantly facing new and unexpected prior authorization requirements for drugs on which they have long-been stable. Establishing guardrails around all prior authorization programs, including prescription drug programs, is critical, and state policymakers should include drug benefits in their prior authorization reform efforts.

- ***Reduce response times:*** Nearly all physicians report that prior authorization delays care and has a negative impact on patients' clinical outcomes (93% and 94%, respectively). When care is delayed, a patient's condition can worsen and disease can progress, often irreversibly. While the Prior Authorization

and Interoperability final rule took steps in the right direction by reducing the maximum response times for prior authorization decisions for medical services, all states should align with current Medicare Part D and Part B drug requirements and establish 24 hours maximum response times for urgent health care services and prescription drugs. Additionally, for non-urgent services and drugs, states laws should go further than federal requirements and require that a plan respond in 48 hours.

- ***Increase transparency:*** Unfortunately, the prior authorization process is an opaque one in terms of when prior authorization is required, the clinical criteria being used, the frequency it is being used, and why it is being used. New federal rules take important steps to improve transparency, and states should build on those rules to reduce the black box nature of these programs so patients can make informed decisions, physicians are able to better navigate the process, and policymakers can make targeted reforms.

    - *Transparency in requirements*: A majority of physicians report that it is difficult to determine whether a prescription medication (65%) or medical service (61%) requires prior authorization, and only 30% of physicians report that the prior authorization information provided in their EHR/e-prescribing system is rarely or never accurate. In order to ensure that patients are fully informed when purchasing a product and making care decisions and that physicians have the information they need to help patients access care, states must require health plans to be transparent about when prior authorization is required and the supporting clinical documentation needed to meet such requirements. The information should be publicly available, accurate and current, and include an effective date to be relied upon by physicians and patients. Additionally, state laws should require that health plans give at least 60-day notice to patients and physicians before new prior authorization requirements take effect.

    - *Transparency when care is denied*: A planned course of treatment is the result of careful consideration and collaboration between patient and physician, and a plan's denial of care requires deviation from this course. But only 1 in 5 physicians always appeal adverse decisions. To increase the transparency of decisions and the likelihood of appeal, state laws should align with the Prior Authorization and Interoperability final rule and require plans to provide specific justification for denials, such as the relevant plan provision, coverage criteria citation, narrative explanation, or an indication that the submitted documentation did not support the request; indicate covered alternative treatment; and detail appeal options. Such information should also communicate actions needed to obtain coverage, whether that be submitting an appeal or additional information or selecting an alternative treatment option identified by the plan.

    - *Reporting of prior authorization data/statistics:* The Prior Authorization and Interoperability final rule also placed requirements on health plans to publish prior authorization data and statistics on their websites to allow for objective evaluation of the efficiency of prior authorization practices. State laws should similarly require health plans to accessibly post on their public websites approval and denial information that includes categories for the requesting physician specialty, the medication or service, the indications for the treatment, the reason for denial, whether a denial was appealed, the outcome of the appeal, and the time between submission and response.

- ***Qualification of health plan reviewer***: Making a medical necessity determination is the practice of medicine. Yet too often health plan representatives making such decisions do not have the needed qualifications or experience. For example, only 16% of physicians participating in peer-to-peer reviews with health plans report that the health plan's "peer" regularly has the appropriate qualifications. Unqualified reviewers make erroneous decisions, threatening patients' health and wasting resources. While many state

policies have focused on having more qualified reviewers at the appeal level, which is valuable, it cannot undo the harm that comes from bad initial determinations. States should build on the 2024 Medicare Advantage final rule and require that, beginning at the initial determination level, health plan reviewers be true peers of the treating physician—in the same specialty, licensed in the same state, and have experience treating the patient's condition.

- ***Ensure the validity of clinical criteria used to determine medical necessity:*** Nearly 1 in 3 physicians report that clinical criteria used by health plans to make medical necessity determinations are rarely or never evidence based. The 2024 Medicare Advantage rule took important steps toward ensuring that MA plans are not frequently using internal or proprietary clinical criteria and recognizing that clinical criteria must be evidence based. State policymakers should build on these MA requirements and clarify that clinical criteria be fully consistent with and reflect generally accepted standards of care, meaning standards of care and clinical practice that are generally recognized by physicians and providers practicing in relevant medical and clinical specialties. Valid, evidence-based sources are recommendations of non-profit physician and health care provider professional associations and national medical specialty societies, including but not limited to patient placement criteria and clinical practice guidelines, and peer-reviewed scientific studies and medical literature.

- ***Reduce the overwhelming volume of prior authorizations***. The volume of prior authorization requirements has become unsustainable for many physician practices and has reached dangerous levels for patients. Most physicians report that the number of prior authorizations required for prescription medications (84%) and medical services (82%) has increased over the last five years. States must act to ensure that prior authorization is used judiciously and rarely, and help right-size these harmful programs.

    - *Require goldcarding programs:* Goldcarding programs allow physicians with high prior authorization approval rates to be exempted from prior authorization requirements. While health plans have opposed these initiatives and made them seem unnecessarily complicated to policymakers, they are targeted volume-reducing strategies. CMS recommended that MA plans implement gold carding programs under the 2024 MA final rule, however, plans are reluctant to adhere, as only 10% of physicians report contracting with health plans that offer programs that exempt physicians from prior authorizations. As such, state policymakers should *require* plans to offer exemption programs and establish appropriate guardrails for implementation.

    - *Use data to identify volume reduction opportunities*: State policymakers can help reduce the volume of prior authorizations by identifying the drugs and services for which authorizations are rarely denied, have high approval rates on appeal, are important to provide expeditiously, disproportionately impact marginalized patients, etc. State law should require collection of prior authorization data for analysis by regulators with the goal of establishing volume-reducing recommendations and action.

Resources for state policymakers and reform advocates

The AMA has a number of resources available to assist in state prior authorization reform efforts including model legislation, survey data, national landscape analysis, and grassroots tools.

- 2024 AMA prior authorization physician survey
- AMA prior authorization model state bill
- Prior authorization state law chart
- Issue brief: Combatting misconceptions about prior authorization
- More resources and grassroot materials at fixpriorauth.org

For more information on state prior authorization reform efforts, contact Emily Carroll, senior attorney, emily.carroll@ama-assn.org.