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CME

Prior Authorization Reforms: The New Reality

New regulations and new pressures on health plans could finally bring change to prior authorization. Here's what you need to know to protect your patients' rights, and your own.

Prior authorizations have been a feature of the American health care system for many years. The health insurance industry has been roundly criticized for its implementation of these programs and in 2018 issued a Consensus Statement for change.[1] Health plans did virtually nothing to fulfill their pledges, so in 2025 they had to reissue a statement of intent,[2] which was met with much fanfare despite being a much watered-down version. Against this backdrop, regulators have finally stepped in. Additionally, a number of states have recently enacted reforms, and Congress has enacted new provisions for national reform of pharmacy benefit managers (PBMs), the vanguard for pharmacy prior authorization. Health plans have begun to respond to the pressure by making some voluntary changes as well.

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Physicians should be aware of these reforms so they can exercise their rights properly within the new rules. Many of the reforms are surprisingly detailed, so this article summarizes the major features.

MEDICARE ADVANTAGE REFORM REGULATIONS

Effective Jan. 1, 2024, the Centers for Medicare & Medicaid Services (CMS) adopted prior authorization reform regulations for Medicare Advantage (MA) plans (CMS-4201-F). These plans must follow traditional Medicare statutes, regulations, National Coverage Determinations (NCDs), and Local Coverage Determinations (LCDs) when making medical necessity determinations. If coverage criteria are not "fully established" in applicable Medicare statutes, regulations, NCDs, or LCDs, MA plans may create their own coverage criteria based on current evidence in widely used treatment guidelines or the clinical literature. Coverage criteria can be characterized as not "fully established" when additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. In this situation, the MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh clinical harms, including from delayed or decreased access to items or services. Further, they must post their coverage criteria on their website and provide a public summary of the evidence they considered.

Approvals granted through PA processes must be valid for as long as medically necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating clinician's recommendation. If a service is initially approved, it may not later be disapproved on medical necessity grounds. MA plans must provide a minimum 90-day transition period when an enrollee who is currently undergoing treatment enters an MA plan, whether the enrollee is new to Medicare or switching from traditional Medicare. During this transition period, the MA organization must not disrupt or require reauthorization for an active course of treatment.

If the MA organization expects to issue a partially or fully adverse medical necessity (or equivalent) determination, meaning they refuse to pay for all or part of the services, that decision must first be reviewed by a physician or other health care professional with expertise appropriate for the services, including knowledge of Medicare coverage criteria. The professional need not be of the same specialty or subspecialty as the treating physician, but must have an unrestricted license to practice.

MA organizations must establish a committee (similar to a Pharmacy & Therapeutics committee), led by a plan's medical director, that annually reviews utilization management policies, including PA, and keeps current with LCDs, NCDs, and other traditional Medicare coverage policies. The regulation specifies that a majority of committee members must be physicians and one member must be independent, having no financial ties with the MA organization.

CMS GENERAL REFORM RULES

CMS adopted an omnibus rule (89 Fed Reg 8758) for multiple programs it regulates, including Medicare, Medicaid, the Children's Health Insurance Program, and the Merit-based Incentive Payment System. The regulations require payers to create several application programming interfaces (APIs), which essentially act as messengers that allow different software programs to interact with each other while maintaining data security and patient privacy, if properly implemented.

In addition to developing and deploying APIs for patient access, provider access, and payer-to-payer access, payers must also develop a prior authorization API. This will enable clinicians and other providers to query directly from their own electronic systems to determine whether a specific payer

KEY POINTS

- Health plans have been slow to change problematic prior authorization practices, but regulators have stepped in with state and federal reforms.
- Reforms include broader use of gold carding, "APIs" that fully support electronic prior authorization workflows, established timeframes for responses, and more options for reviewing and appealing decisions.
- New rules also put restraints on PBMs, which should ease approvals and reduce costs for prescription drugs.

TABLE 1
SUMMARY OF PRIOR AUTHORIZATION REFORMS

Type	Requirements
Medicare Advantage plans (CMS regulations)	• Follow traditional Medicare statutes and coverage determinations for medical necessity decisions, • Create internal criteria only when the above are not fully established; post criteria publicly with evidence justification, • Honor prior authorization approvals for as long as medically necessary; cannot later deny on medical necessity grounds, • Provide a 90-day transition period for new enrollees with ongoing treatment (no reauthorization required), • Establish a utilization management committee, including PA, with a majority of members being physicians, • Ensure adverse determinations are reviewed by a qualified clinician, • Standardize decision timeframes (seven days for standard requests; 72 hours for expedited requests), • Publicly report performance metrics (e.g., denial rates, decision times).
CMS (broader federal programs)	• Develop prior authorization API by Jan. 1, 2027, allowing electronic access to PA rules, including documentation requirements, and decisions across platforms, • Promptly communicate approval, denial (with reason), or the need for more information.
Private payers	**State-specific requirements may include:** • Offer or expand gold card programs, exempting high-performing physicians from some PA requirements, • Honor prior authorizations when patients switch plans, • Require a reasonable duration for authorizations, reducing the need for repeated requests, • Meet mandated turnaround times (typically 24-72 hours for urgent requests; 5-7 days for non-urgent) • Prohibit retrospective denials after approval (except for fraud), • Increase transparency and create evidence-based criteria, • Offer a peer-to-peer appeals process.
PBMs (federal reforms)	• Define PBMs based on function, not title, • Prohibit rebate-based compensation tied to drug price or volume; limit payments to flat "bona fide service fees," • Require repayment ("disgorgement") of improper earnings, • Increase transparency in pricing and performance guarantees, • Establish whistleblower protections (anti-retaliation/anti-coercion), • Require federal oversight and reporting (GAO, MedPAC).

requires prior authorization for a certain item or service and, if so, what documentation the payer requires. In a signal of the lag time health plans often say they need, this rule is to be implemented by Jan. 1, 2027. In a push for transparency, the prior authorization API must be populated with the payer's list of covered items and services (excluding drugs) that require prior authorization, 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 the following:

- Whether the organization approves the prior authorization request, including the date or circumstance under which the authorization ends,
- Whether it denies the request, including the reason for the denial,
- Whether it requires more information.

The regulations establish further rights for patients regarding "organization determinations." These are a health plan's decisions — either pre- or post-service or made concurrently while a patient is receiving services — to provide or pay for services in whole or in part that the patient believes should be furnished. The parties who can request such a determination are the enrollee, their assigned representative, or a physician. The regulations also establish timeframes for issuing determinations (seven calendar days for standard requests and 72 hours for expedited/urgent requests) and require that plans publicly disclose eight specific performance metrics pertaining to denial rates, timing of decisions, and more.

STATE INITIATIVES

The National Association of Insurance Commissioners (NAIC) has published a white paper on prior authorization to advise state regulators regarding options and activities to date.[3] Although all states as well as the District of Columbia and Puerto Rico have some form of prior authorization law, a number of different reforms appear among these state regulations.

One fairly common reform is gold carding, the process by which a physician or other provider may qualify for an exemption from some or all of a health insurer's prior authorization requirements. State regulations usually require health plans to evaluate physicians or other providers for gold card exemptions based on demonstration of appropriate care and high prior authorization approval rates over time. Some health plans have introduced gold card programs voluntarily in states where they aren't legally required, and in those cases exemption requirements vary.

Many state laws also reduce potential disruptions in care by requiring health plans to 1) honor a prior authorization issued by a previous plan when the patient changes coverage and 2) make prior authorizations effective for a reasonable amount of time, rather than expiring quickly and requiring repeat requests. Most state laws also mandate turnaround times on responses to prior authorization requests, generally 24 to 72 hours for urgent requests and five to seven business days for non-urgent requests. The NAIC white paper offers a 15-page grid of state regulations and notes that half of jurisdictions prohibit retrospective denials after an approved request, except in cases of fraud. Just over half of states require plans to base their clinical criteria and medical necessity determinations on evidence-based foundations and be transparent about how they apply the clinical criteria. Similarly, 26 jurisdictions have provisions for peer-to-peer appeals, which often give clinicians an opportunity to discuss the case with a clinician of the same or similar specialty before a decision is final. These state efforts mirror many of the Medicare Advantage rules. Physicians should familiarize themselves with the laws in their state by consulting their state medical society or the NAIC white paper.

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FEDERAL PBM REFORM

PBMs, which act as a middleman and manage prescription drug plan (PDP) benefits for insurers or employers, have been criticized for pocketing rebates, inflating drug prices and premiums, and lowering reimbursement to pharmacies. The antipathy associated with how PBMs operate is evident in the significant reform provisions adopted in the Consolidated Appropriations Act of 2026 (PL 119-75).

The first issue of note is the definition of a PBM (Sec 6224(a)(7)(C)): "The term 'pharmacy benefit manager' means any person or entity that, either directly or through an intermediary, acts as a price negotiator or group purchaser on behalf of a PDP sponsor or prescription drug plan, or manages the prescription drug benefits provided by such sponsor or plan, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered part D drugs, or the provision of related services. Such term includes any person or entity that carries out one or more of the activities described in the preceding sentence, irrespective of

whether such person or entity calls itself a 'pharmacy benefit manager.'"

In other words, the application of the law depends on the functions being performed, not the name of the entity or its characterization. The law prohibits remuneration on any basis except "bona fide service fees,"

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thereby eliminating rebates paid to PBMs based on a percentage of the drug's price, which incentivized higher-priced drugs. Such fees must be a flat-dollar amount and cannot be directly or indirectly based on or contingent upon price, discounts, coverage or formulary placement decisions, or volume or value of referrals. The statute uses the fairly radical term "disgorgement" to refer to the PBM's obligation to return monies received in violation of the law's requirements. It establishes transparency regarding guarantees and cost-performance evaluations. The statute also provides for reporting of alleged violations and establishes anti-retaliation and anti-coercion provisions to protect potential whistleblowers. In addition, Congress charged the Government Accountability Office and the Medicare Payment Advisory Commission (known as MedPAC) with the responsibility to investigate and report on government agreements with PBMs.

CHANGE IS SLOW BUT COMING

Widespread dissatisfaction with the prior authorization process, including PBM activities, has led to new regulatory controls at both federal and state levels. The degree of detail in both is surprising, especially coming out of legislatures that are starkly divided on many national political issues. It speaks to both broad and deep frustrations. Given this volatility, it was somewhat surprising in 2025 when CMS introduced a six-year pilot program (90 FR 28749) using artificial intelligence (AI) to conduct prior authorizations in six states (New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington). The program, which applies only to traditional Medicare and specified services, is referred to as Wasteful and Inappropriate Service Reduction, or WISeR. Many will be watching to see if WISeR lives up to that name.

For physicians, knowing what health plans are supposed to do and understanding the right to challenge prior authorization decisions will be critical going forward. Traditionally, few denials are appealed (11.5% in MA plans), but the percent of denials that are fully or partially overturned when appealed has been very high (80.7% in MA plans).[4] The new rules have introduced real transparency and new timeframes for plans to act, as well as clearly defining the processes they must deploy, the qualifications of those reviewing, and even how AI may be used in prior authorization reviews. It is beyond the scope of this summary to address all the details.[5] But the good news is that physicians should experience change. The history of plans voluntarily reforming themselves has not been good. There is no question that prior authorization, even in a reformed condition, will persist. Physicians should know their rights and pursue them, with legal support as needed, for the good of their patients in the new context. FPM

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