# **Issue**Brief



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Advising Congress on Medicaid and CHIP Policy

## **Prior Authorization in Medicaid**

Prior authorization is the process by which health care payers require that medical providers receive approval before a specific item, service, or medication can be provided (Pestaina and Pollitz 2022). Federal regulations allow Medicaid fee-for-service (FFS) programs and managed care organizations (MCOs) to use prior authorization to limit services in an effort to prevent unnecessary utilization and ensure quality of care (§ 1902(a)(30) of the Social Security Act (the Act), 42 CFR § 438.210). Such limitations aim to ensure that care is necessary, cost-effective, and aligned with clinical standards. While prior authorization can reduce health care costs, it may limit beneficiary access to care through delays and denials of needed medical services, and may place burdens on beneficiaries and providers. Recent federal regulations have sought to reform the Medicaid prior authorization process, and many states have passed or are considering legislation to improve the prior authorization process for Medicaid and other insurance types (American Medical Association (AMA) 2024a, Centers for Medicaid Services (CMS) 2024a).

This issue brief provides background on the prior authorization process and its role in Medicaid, including federal regulations governing prior authorization in Medicaid; its effects on patient safety, program integrity, costs, and access; and key issues with prior authorization for Medicaid providers and beneficiaries.

# **Background on Prior Authorization**

Rising health care spending has led payers, including Medicaid, to adopt strategies to contain costs while maintaining access to high-quality care. In the U.S. health care system, estimates of wasteful spending, which refers to spending that can be lowered or avoided without affecting care quality, range from \$600 billion to over \$1.9 trillion per year (Speer et al. 2020). Public and private insurers' utilization management approaches aim to reduce unnecessary care and manage rising costs. One primary utilization management strategy is prior authorization. Other utilization management strategies include placing limits on the quantity or duration of treatment (i.e., quantity limits), requiring less expensive treatments before approving a more expensive treatment (i.e., step therapy), requiring approval of care during the course of treatment (i.e., concurrent authorization), and denying payment for care after it was delivered (i.e., retrospective review).

Prior authorization—also known as preauthorization, prior approval, or precertification—requires health care providers to obtain approval from a patient's health insurer before providing a specific item, service, or medication (Pestaina and Pollitz 2022). Some studies have shown that prior authorization can reduce health care costs without negatively impacting care quality (Asher et al. 2020, Asher et al. 2019). However, there may be serious unintended consequences of prior authorization for beneficiaries. A recent U.S. Department of Health and Human Services Office of the Inspector General (HHS OIG) report highlighted concerns that prior authorization can reduce access to care through the delay or denial of medically necessary medications and services (OIG 2022). A 2023 survey of adults with health insurance (Medicaid, Medicare, exchange, or employer-sponsored coverage) found that 16 percent of those surveyed experienced problems with prior authorization in the preceding year, which sometimes resulted in delayed or denied care and declines in health (Pollitz et al. 2023). Moreover, provider groups have emphasized that the prior authorization process is administratively burdensome and costly (AMA 2024b).

#### Prior Authorization in Medicaid

State Medicaid agencies and MCOs have flexibility to determine the medications and services for which they will require prior authorization (§ 1902(a)(30) of the Act and 42 CFR § 438.210). Examples of Medicaid services that

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1800 M Street NW Suite 650 South Washington, DC 20036 commonly require prior authorization include non-emergency medical transportation, durable medical equipment (DME), behavioral health services, inpatient hospital stays, inpatient and outpatient surgeries and procedures, rehabilitation services, and nursing facility services (KFF 2018). States cannot impose prior authorization requirements for any screening services provided under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit (CMS 2014). States may prohibit prior authorization for some specific items, services or medications. For example, Medicaid plans in the District of Columbia cannot require prior authorization for medications to treat opioid use disorder (OUD), emergency services, or pre-hospital transportation (DC Code § 31–3875 2024).

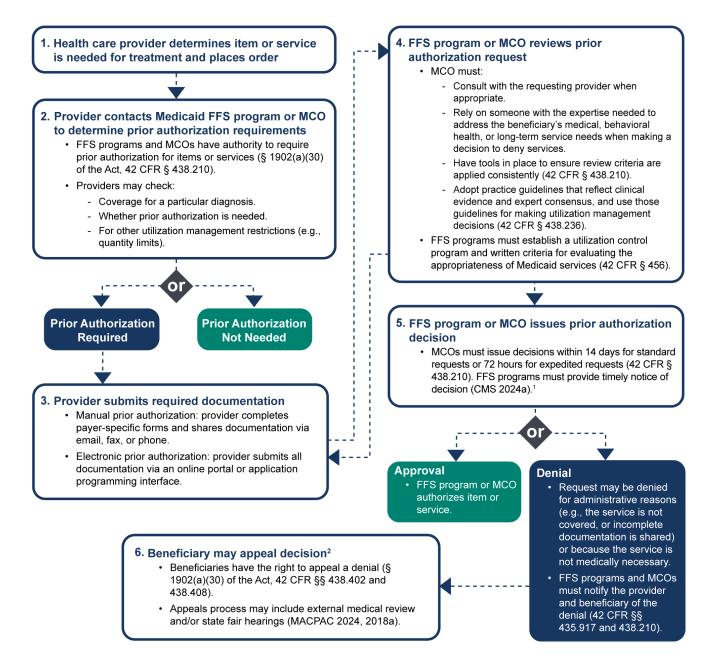
The types of services and medications that require prior authorization can vary between Medicaid FFS programs and Medicaid MCOs. For example, a study of prior authorization requirements for medications to treat OUD found that among programs and plans that covered these medications, a higher percentage of FFS programs (64.1 percent) than of MCOs (42.3 percent) required prior authorization for buprenorphine. In contrast, a slightly higher percentage of MCOs (35.6 percent) than of FFS programs (30.8 percent) required prior authorization for methadone (Abraham et al. 2022).<sup>2</sup>

Prior authorization is also frequently required for prescription drugs. Many MCOs use a formulary that lists drugs that the plan encourages providers to prescribe over others (e.g., generic instead of brand-name drugs). For FFS programs, this list of preferred drugs is called a preferred drug list (PDL). FFS programs and MCOs may require prior authorization for drugs that are not considered preferred on the formulary or PDL. They also can limit the number of prescriptions a beneficiary can receive without prior authorization (Gifford et al. 2020).

#### The Prior Authorization Process in Medicaid

To request prior authorization, health care providers submit clinical and administrative information for the FFS program or MCO to review and issue a prior authorization decision (Pestaina and Pollitz 2022). While MCOs are required to make prior authorization decisions within a certain time frame and expedite requests if beneficiaries need urgent medical care, states may choose to impose shorter times than specified in federal regulations. Currently, CMS does not require state FFS programs to issue prior authorization decisions within a specific timeline (42 CFR § 438.210, CMS 2024a). Figure 1 provides an overview of the current prior authorization process for medical items and services. Recent federal rulemaking will place new requirements on MCOs and FFS programs, as detailed later in the brief.

FIGURE 1. Current Medicaid Prior Authorization Process for Medical Services and Items



Notes: This process diagram does not apply to prescription drugs. FFS is fee-for-service. MCO is managed care organization.

**Sources:** §§ 1902(a)(3) and 1902(a)(30) of the Act; 42 CFR §§ 435.917, 438.210, 438.236, 438.402, 438.408, and 456; CMS 2024a; MACPAC 2024, 2018a.

<sup>&</sup>lt;sup>1</sup> Upcoming changes required by the Interoperability and Prior Authorization final rule (i.e., adding a time frame for decisions for Medicaid FFS programs and updating the existing time frame for MCOs for standard requests from 14 days to 7 days) are not reflected in this figure (CMS 2024a).

<sup>&</sup>lt;sup>2</sup> MACPAC has conducted separate work on appeals in Medicaid managed care, as described in Step 6 (MACPAC 2024).

In straightforward cases, the provider submits the necessary documentation to demonstrate the necessity of the care, the insurer reviews and approves the prior authorization request, and the service or item is provided to the patient. However, as discussed below, the prior authorization process can vary from the standard process depicted in Figure 1.

Peer-to-peer review. Peer-to-peer review is a supplemental review option offered in some prior authorization cases. In a peer-to-peer review, the requesting provider and a provider affiliated with the insurer discuss the medical necessity of the care sought to assess its clinical appropriateness (O'Reilly 2023a). Currently, there are no federal definitions or requirements for peer-to-peer reviews, and this option is not available to all providers or for all requests. MCOs may offer peer-to-peer review as an option when there is an intent to deny a prior authorization request, to assess whether the denial is clinically appropriate (Aetna 2020). Prior authorization reviewers may also ask for these reviews if additional clinical insight is needed, or they may be triggered based on the payer's clinical guidelines and protocols (e.g., for high-cost or high-risk treatments). For Medicaid MCOs, this review is an additional step taken outside of the requirement that MCOs consult with the provider when necessary to make a prior authorization decision (42 CFR § 438.210). One study of billing records from a highvolume, academic radiation medicine department noted that all of the denied prior authorization requests for radiotherapy treatment included in the study were referred for peer-to-peer review, which suggests that in some cases, the review process may automatically include a peer-to-peer review (Koffler et al. 2022). However, peer-topeer reviews can complicate the prior authorization process through back-and-forth communication, which may create further care delays or involve a reviewing provider from a different specialty who has limited clinical experience with the requested care (O'Reilly 2023a).

**Retrospective denials.** Prior authorization approvals are not binding, and usually contain language stating that the approval does not guarantee payment. This non-binding approval allows payers to retrospectively review the services or products after they are provided and deny payment for the care. Denials that occur after care is approved and provided can stem from payers redefining care as experimental or unnecessary, or providers requesting prior authorization for one service code but billing for another (Gaines et al. 2020).

Concurrent review and other requirements. Concurrent review is a utilization management strategy where the need for care is re-assessed during the course of treatment. For example, an initial prior authorization for an inpatient hospitalization may be for a specified number of days, and additional approval would be required if the stay needs to be extended. A medication may be approved for a limited time, requiring ongoing approval in order to continue treatment. Payers also may place additional clinical or administrative conditions on providers and beneficiaries for prior authorization approval. For example, prior authorization requirements for buprenorphine in Medicaid can include patient education and ongoing patient surveillance, such as pill counting or routine or random drug testing (Tiako et al. 2023).

Prescription drugs. The prior authorization process for prescription drugs is similar to that depicted in Figure 1, with some differences in that it includes both the prescribing provider and the dispensing pharmacy. If the prescribing provider has not fulfilled the prior authorization requirements, the prescription will be flagged as needing prior authorization before the pharmacy can dispense the drug. Some types of prior authorization may be automatically approved or handled by the pharmacy, such as dispensing the generic version instead of the brand version written on the prescription. If additional information is needed for approval, the pharmacy will work with the prescribing provider, who is responsible for ensuring that the information needed for prior authorization is submitted. While many pharmacy utilization management tools are essentially variations of prior authorization, they are referred to using different terminology, including:

• **Formulary/Preferred drug lists:** A formulary (under Medicaid managed care) or PDL (under Medicaid FFS) provides a list of drugs that are considered preferred and covered without prior authorization, which generally include lower cost drugs such as generic versions or drugs for which the MCO or state has negotiated a rebate in exchange for preferred status (Ovsag et al. 2008).

- **Step therapy**: Step therapy requires that a preferred drug for a medical condition is prescribed and tried first before other drugs for that condition will be approved for coverage.
- Quantity limits: Quantity limits are limits on the amount of a drug that will be covered (e.g., seven-day supply) that generally reflect medically accepted maximum daily doses and length of therapy. Quantity limits may also be placed on the number of prescriptions a beneficiary can receive in a given month before additional approval is required.

# Federal Requirements for Prior Authorization in Medicaid FFS and Managed Care Programs

Use of prior authorization by state Medicaid FFS programs and MCOs is subject to several requirements that aim to ensure that the process is fair and transparent and does not impede access to necessary care. States have authority over prior authorization practices in Medicaid and can implement prior authorization regulations that are stricter than federal requirements (Medicaid Health Plans of America (MHPA) 2023).

#### Federal Requirements for Prior Authorization in Medicaid

Medicaid statute provides authority for utilization review in Medicaid (§ 1902(a)(30) of the Act). States can develop methods and procedures that aim to limit unnecessary utilization of medical care and services in their FFS programs and MCOs (42 CFR §§ 440.230 and 438.210). Additionally, Medicaid FFS programs and MCOs cannot arbitrarily deny a service based on a beneficiary's diagnosis or illness type (42 CFR §§ 440.230 and 438.210).

**Specific federal requirements for Medicaid FFS programs.** Federal regulations require FFS programs to establish a utilization control program and written criteria for evaluating the appropriateness of Medicaid services (42 CFR § 456). Further, FFS programs must provide timely and adequate written notice of any decisions regarding a denial of benefits or services, or a change in the level of benefits or services covered (42 CFR § 435.917, CMS 2017).

Specific federal requirements for Medicaid MCOs. MCOs are subject to additional requirements meant to ensure that they do not use prior authorization to restrict access to medically necessary care (OIG 2023). First, medical services provided by MCOs must be comparable to services provided in FFS programs in amount, duration, and scope (42 CFR § 438.210). MCOs must also adopt practice guidelines that reflect clinical evidence and expert consensus, and use those guidelines for making utilization management decisions (42 CFR § 438.236). Federal regulations also detail the processes and timelines by which MCOs must make prior authorization decisions. MCOs must have tools in place to ensure that prior authorization review criteria are applied consistently, and any MCO decisions to deny services must be made by individuals with appropriate clinical expertise to address the beneficiary's health care needs. MCOs must also supply denial notifications to requesting providers and give beneficiaries a notice of denial in writing. Current regulations require that standard decisions be made within 14 days and expedited decisions be made within 72 hours, though these time frames will be reduced by the new requirements from the 2024 Interoperability and Prior Authorization final rule, which will take effect January 2026 (42 CFR § 438.210, CMS 2024a).

Additional federal requirements for mental health parity. Medicaid alternative benefit plans (ABPs), Title XXI State Children's Health Insurance Program (CHIP) programs, and MCOs are subject to certain provisions of the Mental Health Parity and Addiction Equity Act (MHPAEA), as amended by the Patient Protection and Affordable Care Act (ACA, P.L.111-148, as amended), which has requirements for the application of utilization management for behavioral health services. The MHPAEA Application of Mental Health Parity Requirements final rule from 2016 specified these requirements for ABPs, CHIP, and MCOs (CMS 2016a). Specifically, these impacted payers are prohibited from applying more stringent utilization management requirements to behavioral health benefits

than are applied to general medical services (CMS 2016a).<sup>3</sup> Further, MCOs are required to provide the criteria for medical necessity determinations for behavioral health benefits to beneficiaries and contracting providers upon request, and to provide the beneficiary with the reason for any denial of payment for behavioral health services (42 CFR § 438.915, CMS 2016a).

#### Oversight of Prior Authorization

MCOs are subject to oversight by state Medicaid agencies, which are required to contract with external quality review organizations (EQROs) to conduct regular reviews of MCOs (42 CFR §§ 438.66 and 438.310 - 438.370). These reviews must include information on MCOs' compliance with standards in subpart D of 42 CFR Section 438.66, including the standards for authorization of services in 42 CFR Section 438.210 (CMS 2023, 42 CFR § 438.358(b)(1)(iii)). While the EQRO review guidance does not require collection of specific data elements related to utilization management, or that EQROs assess whether prior authorization denials are clinically appropriate, CMS does include optional guidance for interviewing utilization management staff and assessing utilization management policies and procedures (CMS 2023). Beginning in 2026, FFS programs will be subject to transparency and reporting requirements on prior authorization practices (42 CFR § 440.230).

#### 2024 Interoperability and Prior Authorization Final Rule

The Advancing Interoperability and Improving Prior Authorization Processes final rule aims to reduce prior authorization decision timelines, increase transparency of prior authorization decisions and metrics, and enhance interoperability and data exchange (CMS 2024a). These changes apply to Medicaid and CHIP FFS and MCOs, as well as Medicare Advantage (MA) plans and Qualified Health Plans (QHPs)—collectively referred to as "impacted payers." Prescription drugs and drugs covered under the medical benefit, such as physician-administered drugs, are excluded from this rule. The rule includes several key provisions:

- **Decision time frames and reasons.** Starting January 1, 2026, the rule requires impacted payers to make prior authorization decisions within seven calendar days for standard requests and 72 hours for expedited requests. The rule also requires payers to provide a specific denial reason for denied prior authorization decisions to the requesting provider, regardless of the method used to send the prior authorization request (i.e., the request does not have to come through the application programming interface (API) for prior authorization).
- Transparency and reporting. The rule requires impacted payers to publicly report certain prior authorization metrics on their websites annually by March 31 of each year, beginning in 2026. These data will be reported in aggregate across all services and items, and include metrics such as the percentage of standard prior authorization requests that were approved or denied.<sup>5</sup>
- Electronic prior authorization. The rule requires impacted payers to implement and maintain four APIs— prior authorization, patient access, provider, and payer-to-payer—that follow a set of interoperability standards (i.e., Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®)) by January 1, 2027. The prior authorization API will include a list of covered items and services, identify documentation needed for a given prior authorization request, support the submission of a prior authorization request, and facilitate the sharing of a prior authorization decision from the payer to the provider. Providers may use the prior authorization API to check prior authorization requirements electronically at the point of ordering the service or item and identify the needed documentation to initiate the prior authorization request. The patient access API will include information for patients about the prior authorization request, including the status of the request and reason for any denied request. The provider API is intended to facilitate communication between in-network providers by sharing patient data among their providers. Finally, the payer-to-payer API is intended to support care continuity by sharing patient data across payers when there is a transition in coverage.

#### **Covered Outpatient Drugs**

Under the Medicaid Drug Rebate Program, state Medicaid programs must generally cover all of a participating manufacturer's drugs when prescribed for a medically accepted indication (§ 1927(a) of the Act). Medicaid statute requires that any drug excluded from a formulary must be covered to some extent through a prior authorization program (§ 1927(d)(4)(D) of the Act). Because states cannot exclude coverage of most drugs, prior authorization is the primary tool Medicaid has to manage utilization and spending for prescription drugs (§ 1927(d) of the Act, 42 CFR § 438.3(s)). Although there is some flexibilty in how state FFS programs and MCOs can use prior authorization to limit the use of a particular drug, the effect of those limitations "should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments" (CMS 2015b).

Additionally, FFS programs and MCOs must comply with statutory requirements for prior authorization programs for covered outpatient drugs. Specifically, FFS programs and MCOs must respond to a prior authorization request for a covered outpatient drug within 24 hours of the request and dispense a 72-hour supply of the drug in emergency situations (§ 1927(d)(5) of the Act).

# Impact of Prior Authorization

Prior authorization aims to ensure that care is medically appropriate and cost-effective by limiting beneficiary access to unnecessary care while preserving access to needed services. In addition, prior authorization can limit improper, fraudulent, or wasteful payments by reducing use of services, items, and medications that have historically been overused or misused. Research on whether prior authorization achieves cost savings is somewhat mixed, and findings are typically specific to certain payers or services. Despite the goal of reducing unnecessary care, there is some evidence that prior authorization can also be a barrier to access to care in some circumstances.

#### Promoting Patient Safety and Clinically Appropriate Care

Prior authorization aims to ensure that delivered services, items, and medications are medically appropriate and safe. Appropriateness of medical care can be defined by the care itself, and also by the setting in which it is provided (Lavis and Anderson 1996). Prior authorization can be used to evaluate both. First, appropriate care aligns with evidence-based clinical standards and is expected to benefit the patient. For example, surgical treatment is appropriate for some types of cancers (e.g., colorectal) and inappropriate for other types of cancers (e.g., leukemia) (National Cancer Institute (NCI) 2024, 2015). Second, appropriate treatment settings align with the severity of the patient's condition and their treatment needs (Lavis and Anderson 1996). Some types of care are more appropriate in outpatient settings (e.g., certain surgical procedures), while other types of care should be provided in inpatient settings (e.g., acute stroke treatment) (National Institutes of Health, National Heart, Lung, and Blood Institute (NIH NHLBI) 2023, UnitedHealthcare 2023). Prior authorization can be used to direct care to the least restrictive setting, which may benefit patients (MHN 2024, Anthem 2022). For example, providing surgical care in appropriate outpatient settings rather than inpatient settings can reduce the risk of a surgical site infection (Patient Safety Network Agency for Healthcare Research and Quality (PSNET AHRQ) 2019).

Prior authorization can promote appropriate care when policies are based on clinical guidelines. For example, some FFS programs and MCOs apply prior authorization to pediatric attention-deficit/hyperactivity disorder (ADHD) medication prescribing (Center for Public Health Law Research (CPHLR) 2023a, 2023b). The American Academy of Pediatrics (AAP) clinical guidelines for medication treatment of ADHD vary by age. The AAP recommends behavioral interventions as the first-line treatment for most children age four to five, whereas medication can be included as a first-line treatment for children age 6 to 11 (Wolraich et al. 2019). As of April 2023, 34 Medicaid FFS programs applied prior authorization to ADHD medications prescribed to children under 18. Of these, 28 programs applied the prior authorization age restrictions to all medications (i.e., preferred and non-preferred medications). Of the 28 FFS programs with prior authorization requirements for some preferred ADHD medications, 15 programs applied the requirements only to children under age 6(CPHLR 2023a). A legal

assessment found that some, but not all, state Medicaid prior authorization policies for ADHD medications analyzed were linked to AAP treatment guidelines (Hulkower et al. 2017).

Payers use prior authorization to address unsafe prescribing practices. For example, prior authorization is a recommended component of antibiotic stewardship programs, which aim to improve antibiotic prescribing and use and prevent antibiotic resistance (CDC 2019). Some payers have also required prior authorization for ivermectin, a parasitic infection medication that is not FDA-approved for the treatment of viral diseases such as COVID-19 (NIH 2023). This ensures that the medication is being prescribed only for conditions that the FDA approved it to treat (CareFirst 2021).

#### **Program Integrity**

Prior authorization can be used to limit improper, fraudulent, and wasteful payments, with some evidence of success. For example, prior authorization demonstrations in Medicare that aimed to address program integrity for select services and items were estimated to produce savings of between \$1.1 billion and \$1.9 billion as of March 2017. However, it was difficult to disentangle the effects of these demonstrations from other program integrity efforts (U.S. Government Accountability Office (GAO) 2018).8

Prior authorization can also reduce use of prescription medications that have historically been misused or diverted, such as opioids prescribed for pain. A study of Pennsylvania's Medicaid program found that enrollees in plans with prior authorization for opioids prescribed for pain had lower rates of opioid misuse (Cochran et al. 2017). Oregon's Medicaid program developed a prior authorization program for high-dose opioids, which was effective at reducing high-dose prescription fills (Hartung et al. 2018). However, prior authorization to prevent medication misuse may also hinder access for appropriate use of opioid medications used to treat OUD (Tiako et al. 2023). Buprenorphine is a safe and effective medication for the treatment of OUD, but concerns about potential diversion (i.e., channeling prescription drugs into illegal markets) mean that it is commonly subject to prior authorization, which may lead to treatment delays or disruptions in continued care (Tiako et al. 2023, CMS 2012).

#### **Cost Implications**

While a key goal of prior authorization is to reduce health care spending, evidence of prior authorization's effects on spending varies, and studies are often focused on specific items, services, or medications that may be difficult to generalize. One study of the Medicare Part D Low-Income Subsidy (LIS) program found that current prior authorization policies reduced net drug spending by \$96 per patient, or 3.6 percent (Brot-Goldberg et al. 2023). Analyses of state Medicaid prior authorization policies for lipid-lowering drugs in Indiana and Michigan and buprenorphine in Massachusetts found that they led to a switch to preferred drugs and a decrease in cost (Clark et al. 2014, Lu et al. 2011). However, an analysis of prior authorization policies for second-generation antipsychotic drugs in Texas and West Virginia found that the policies did not reduce drug spending (Law et al. 2008).

Initial savings can be offset by potential adverse effects of delayed or denied medical care. For example, increased use of alternative therapies can be associated with higher costs, of the alternate treatment itself, or other disease-related costs. One analysis found that while prior authorization in Medicaid for pregabalin, which treats two nerve pain conditions, helped control access to the medication, the prior authorization policy was associated with increased costs from use of other pain management treatments, such as opioids (Margolis et al. 2009). Similarly, prior authorization might pose a barrier to treatments that would produce long-term cost savings. For example, prior authorization for tobacco cessation treatments could lead to short-term cost savings but also to higher health care expenditures in the long term to treat smoking-related diseases such as lung cancer and cardiovascular conditions (DiGiulio et al. 2018).

Prior authorization may also create Medicaid cost savings by strengthening state Medicaid agencies' supplemental drug rebate negotiating power. 10 The ability to create a PDL and apply prior authorization to specific

medications gives state Medicaid agencies leverage when negotiating supplemental rebates with drug manufacturers (Dolan 2019). Manufacturers provide these rebates to ensure that their medications are placed on a state's PDL or have fewer restrictions (MACPAC 2018b). Limited or lower supplemental rebates could contribute to increased pharmacy expenditures for state Medicaid programs (Bachhuber 2020).

In addition to mixed findings on prior authorization's ability to reduce Medicaid spending for FFS programs and MCOs, prior authorization may generate costs through the burden it imposes on health care providers by diverting staff time and resources. In 2019, prior authorization was the costliest medical transaction, costing providers \$11 per manual transaction and \$4 per web portal transaction (CAQH 2020). In 2023, 35 percent of physicians reported having staff who work exclusively on prior authorization (AMA 2024b). Health plans must spend money on prior authorization reviews and systems; however, these costs may be offset by savings from decreased utilization of services subject to review, and using prior authorization may also help keep beneficiary plan premiums low (Busch and Fielek 2023, CAQH 2020).

#### Access to Care

Evidence suggests that when prior authorization is applied, use of the applicable service or item decreases, beneficiaries may experience delays in receipt of care, and providers may alter their clinical decisions. Change in access to care associated with prior authorization is evidenced by (1) decreased use of a treatment when a prior authorization policy is implemented or (2) increased use of a treatment when a prior authorization policy is removed. In the case of OUD medications, an analysis of 34 states and the District of Columbia found that Medicaid prior authorization policies were associated with reduced likelihood of buprenorphine treatment episodes that continued for at least six months (Landis et al. 2022). An analysis of two state Medicaid programs (California and Illinois) that lifted prior authorization requirements for buprenorphine found that the policy change was associated with a statistically significant increase in buprenorphine prescription fills in one state (Keshwani et al. 2022). Decreased care use when a prior authorization policy is implemented and increased care use when a prior authorization policy is lifted suggests that prior authorization may be a barrier to Medicaid beneficiaries' access to care.

Prior authorization processes, even when they produce clinically appropriate decisions, can delay patient access to care. The effects of care delays on patient outcomes can range from minor (e.g., waiting for a genetic test for hereditary cancer susceptibility that comes back negative) to severe (e.g., hospitalization). There is limited research and evidence on the minor effects of prior authorization on patient outcomes; however, there are examples of prior authorization's effects on individual patient outcomes. One study found an association between prior authorization for oral anti-cancer drugs and delays in treatment receipt among patients with new prescriptions for these medications (Lichtenstein et al. 2021). Delays in treatment initiation for certain cancers are associated with an increased risk of mortality (Khorana et al. 2019).

Prior authorization can produce clinically inappropriate denials of care that may lead to adverse patient outcomes. For example, one patient who had a prior authorization request for a medication denied became septic, leading to a 39-day hospital stay, and then responded well to the medication when it was approved—70 days after it was originally prescribed (Jew et al. 2020). Additionally, a patient who had previously received an anti-seizure medication through Medicaid was not able to fill a new prescription due to lack of prior authorization. The patient was unable to pay for the medication out of pocket and had a fatal seizure before the prior authorization documentation issue could be resolved (Correa v. Schoeck 2016).

Finally, there is evidence that prior authorization requirements can influence clinical decision making. In a survey-based study of prior authorization requirements and clinical decision making, some providers reported modifying diagnoses to obtain prior authorization or prescribing a different medication to avoid prior authorization delays (Salzbrenner et al. 2023). Sixty-nine percent of surveyed physicians reported that prior authorization requirements led to ineffective initial treatments, and 68 percent reported that prior authorization requirements led to additional office visits (AMA 2024b).

# **Key Issues and State Efforts in Medicaid Prior Authorization**

The use of prior authorization raises a number of issues for state Medicaid agencies, MCOs, providers, and patients. First, there is variation and lack of transparency in how clinical criteria for determining medical necessity are developed. Second, the prior authorization process imposes burdens on patients, providers, and payers, and there is evidence that prior authorization may not be applied equitably. Finally, lack of transparency over prior authorization requirements further complicates and delays the process; and lack of information about approvals, denials, and appeal outcomes limits understanding of the impact of prior authorization and hinders oversight efforts.

#### Clinical Criteria for Determining Medical Necessity

Prior authorization decisions are based on determining the medical necessity of the requested service, item, or medication. Federal regulations require (1) that FFS programs establish written criteria for evaluating the appropriateness of Medicaid services, and (2) that MCOs adopt practice guidelines for utilization management that reflect clinical evidence and expert consensus (42 CFR §§ 438.236 and 456). Additionally, MCOs may not define medically necessary services in a manner that is more restrictive than what is used in FFS (42 CFR § 438.210).

There is variation across FFS programs and MCOs in how clinical criteria are developed. State Medicaid agencies or MCOs may develop clinical criteria internally (e.g., based on utilization or other metrics); draw from external sources such as peer-reviewed medical literature, government agencies, or medical associations; or purchase clinical criteria from third-party vendors (GAO 2024, MHPA 2023). Clinical criteria can vary across Medicaid FFS programs and MCOs, and these criteria can change over time as new clinical evidence becomes available.

Some states set requirements for how clinical criteria for prior authorization decisions are developed that apply to Medicaid. These clinical guidelines cannot conflict with federal or state prior authorization rules (e.g., they cannot arbitrarily deny care). Certain payers (including Medicaid and CHIP) in Illinois are required to establish clinical review criteria that align with a national medical accreditation entity and are based on evidence and nationally accepted standards except when standards are provided by state law (IL Stat. 215 ILCS 200 2023). In Nebraska, state law allows payers (including Medicaid) to develop their own internal clinical criteria and purchase or license clinical criteria from qualified third-party vendors (NE Code § 44-5426 2023). The GAO assessed prior authorization processes for diagnostic and treatment services under the EPSDT Medicaid benefit of five selected MCO plans and found that all plans used state criteria when available; two used internal criteria, and three used criteria from third-party vendors. MCOs may choose to develop internal clinical criteria because criteria from third-party vendors are sometimes more restrictive than state FFS requirements (GAO 2024).

There is also variation in how clinical criteria are documented in Medicaid. Some MCO websites list information about the source(s) of their clinical criteria. In Louisiana, payers (including Medicaid) must document that their prior authorization programs use evidence-based clinical review criteria and have a plan for reviewing and updating these criteria (LA Rev. Stat. § 22:1260.42 2023).

Prior authorization requests for a specific treatment that are almost always approved by the payer might indicate that prior authorization is unnecessary for the treatment and may limit patient access to important treatment. For example, one study found that 85 percent of almost 900 prior authorization requests for immunosuppression medications after organ transplant were approved. Patients who were insured by Medicaid experienced almost half of the denials (46 percent). Immunosuppression medications for organ transplant recipients are the standard of care, and applying prior authorization could delay receipt of immunosuppression medications and contribute to adverse patient outcomes (Muran et al. 2023). Clinical criteria for prior authorization are not static and can be

updated to align with evolving standards of care that accompany advancements in medicine. Payer data on prior authorization may help flag services, items, and medications to review.

#### Administrative Burden and Costs

Prior authorization may impose significant administrative burdens on patients and providers. For patients, prior authorization can involve engaging with providers and their staff, as well as the payer, to facilitate authorization. A survey of adults with health insurance showed that 22 percent of those insured by Medicaid experienced problems with prior authorization in the past year (Pollitz et al. 2023). Another survey of patient experiences with prior authorization in cancer care found that 67 percent of patients reported that they had to get involved in the prior authorization process through phone calls or appeals of denials. Twenty percent of patients reported that they, or a caregiver, spent 11 hours or more on the prior authorization process (Chino et al. 2023).

Prior authorization can also pose significant burden for providers through administrative, financial, and technological challenges. Some state Medicaid agencies, such as Alaska's, have different prior authorization entities for different types of care, such that providers must request prior authorization by calling the appropriate vendor for a given service (Alaska Department of Health 2024). Providers spend significant time and resources processing prior authorization requests, especially when the prior authorization is performed manually (fax or phone), when the payer requests additional documentation, or when a prior authorization request is denied. A physician survey reported that practices complete 43 prior authorization requests per physician each week on average, and physicians and their staff spend 12 hours per week completing prior authorization requests (AMA 2024b).

Though many prior authorization reform efforts have focused on electronic prior authorization portals to improve efficiency, adoption of this technology can be costly and challenging for providers. In 2022, only 29 percent of physicians reported having an electronic health record system that allows for electronic prior authorization of prescription drugs (AMA 2022).

Several payers recently removed prior authorization requirements for specific services that accounted for a relatively large volume of their prior authorizations (O'Reilly 2023b). In 2023, UnitedHealth Group removed approximately 20 percent of prior authorization requirements across its Medicaid, MA, and commercial plans (Tepper 2023a). In 2023, Cigna removed prior authorization requirements for 600 procedures in its commercial plans, which accounted for about 25 percent of the prior authorization requirements for enrollees in these plans (Tepper 2023b).

## **Health Equity**

Prior authorization has been linked to health equity concerns, with evidence suggesting that certain groups face disproportionate prior authorization requirements or denials. The following types of disparities in prior authorization have been identified in the literature:

**Insurance type.** Evidence suggests that individuals covered by Medicaid may be negatively impacted by prior authorization more often than other insurance types. One study that investigated prior authorization for a hepatitis C medication in four states found that a much higher proportion of patients covered by Medicaid received a prior authorization denial for their medication (46 percent) than patients covered by Medicare (5 percent) or commercial insurance (10 percent) (Lo Re et al. 2016). Similarly, the HHS OIG found that in 2019, reviewed Medicaid MCOs denied prior authorization requests twice as often as MA organizations (12.5 percent versus 5.7 percent) (OIG 2023).

**Region.** There is evidence of regional disparities in the use of prior authorization. HHS OIG found that average prior authorization denial rates in Medicaid managed care varied widely between MCOs, both within and across states. MCO denial rates ranged from as high as 41 percent for an MCO in Illinois to as low as 2 percent for two MCOs in Pennsylvania. MCOs within a given state sometimes had very different denial rates. In the HHS OIG

study, denial rates for seven of the Texas MCOs ranged from 6 percent to 34 percent, with a median denial rate of 13 percent (OIG 2023). Additionally, one study found that QHPs in the South were 16 times more likely to require prior authorization for pre-exposure prophylaxis (PrEP), a medication used to prevent HIV, than QHPs in the Northeast (McManus et al. 2020). 13

Race and ethnicity. Prior authorization may also be applied disproportionately across racial and ethnic groups. One study of patients at a gynecologic cancer center found that a higher proportion of Asian American patients experienced prior authorization (37 percent), compared to Hispanic patients (18 percent), Black patients (20 percent), and white patients (23 percent) (Smith et al. 2023). From a provider perspective, the administrative burden of prior authorization also has implications for health equity. Prior authorization could disproportionately impact lower-resourced providers that have fewer resources available to process prior authorization requests (ABC 2019).

#### Transparency and Reporting

Key issues have emerged surrounding transparency in the prior authorization process and the information made available to beneficiaries, providers, and the public. Beneficiaries and providers need ready access to general information about prior authorization requirements to inform clinical decision making, and to information related to specific prior authorization requests that are in progress. For providers, knowing which services require prior authorization, and the documentation needed for a request to be approved, can reduce delays in treatment and increase efficiency (AMA 2018). Prior authorization determination time frames may be shortened through greater transparency in provider access to prior authorization documentation requirements and denial reasons, as well as faster exchange of information between providers and payers.

Public reporting and/or reporting to state entities increases payer accountability by providing a mechanism to track the use and impact of prior authorization. Reporting information, such as prior authorization approval and denial rates for specific services, is a component of ensuring accountability and transparency in prior authorization and helps with the prior authorization oversight process. Lack of data on prior authorization requests, approvals, and denials can inhibit oversight of health plans and assessment of whether prior authorization is working as intended. Moreover, published information on prior authorization approval and denial rates could inform beneficiary health plan selection. As of January 2023, nine states and the District of Columbia publicly report some information about prior authorization denials (MACPAC 2024).<sup>14</sup>

There are currently no federal requirements for reporting data on prior authorization requests, approvals, and denials (MACPAC 2024). A recent HHS OIG audit of prior authorization in Medicaid managed care made several recommendations regarding public reporting, including that CMS require states to collect data on MCO prior authorization decisions (i.e., the number of decisions each MCO issued that were "favorable, partially adverse, and adverse" to enrollees) and issue guidance to states on using that data for oversight of MCOs (OIG 2023). Some states already require reporting on prior authorization data, either on a payer's website or through required submission of information to state Medicaid agencies or health departments. For example, in Washington, plans must annually submit data to the state on prior authorization statistics for specific services, including service codes with the highest number and percent of approved and denied prior authorization requests and the average prior authorization response times for standard, expedited, and extenuating-circumstances requests (AMA 2024). <sup>15</sup>

The new Interoperability and Prior Authorization final rule addresses concerns with both transparency and reporting. The rule promotes transparency for patients and providers by requiring impacted payers to share information with other entities via the new APIs, including the sharing of (1) information about prior authorization with patients; (2) prior authorization requests and decisions (excluding drugs), including specific reasons for denials, with providers; and (3) prior authorization details with other payers (CMS 2024a). It also addresses concerns with reporting by requiring impacted payers to publicly report prior authorization metrics on their websites each year. However, these metrics will be aggregated across all items and services (at the plan level for MCOs and the state level for FFS programs) and are only required to be posted on payer websites, rather than collected and published by state Medicaid agencies. Some stakeholders have suggested that CMS require more

granular reporting of prior authorization metrics, or that the data be reported to CMS or state Medicaid agencies to improve prior authorization oversight (CMS 2024a).

#### Trends in State Prior Authorization Laws and Regulations

States have passed a range of legislation to address the concerns discussed above (AMA 2024a). <sup>16</sup> These reform efforts, defined below, target the described challenges associated with the prior authorization process:

- Gold carding: Exempts a provider temporarily from prior authorization requirements for a certain medication
  or service when the provider achieves a specified percentage of prior authorization approvals for the given
  medication or service within a fixed time period.
- **Electronic prior authorization**: Requires that plans implement automated electronic prior authorization systems or electronic portals as an alternative to traditional prior authorization mediums.
- Exceptions: Exempts certain medications or services from prior authorization requirements.
- Shortened decision timelines: Requires plans to issue prior authorization decisions sooner than federally
  established timelines.
- Limits on retrospective denials: Limits denials of payment after the medication or service was provided.
- Clinical criteria: Sets standards for developing the clinical criteria informing prior authorization decisions.
- Prior authorization reviewer requirements: Requires that adverse prior authorization decisions or appeal
  decisions must be made by people with specific license requirements or clinical training, and/or people who
  do not have a financial incentive.
- **Transparency requirements**: Requires payers to publish their prior authorization requirements and to provide the clinical basis for prior authorization decisions to the provider.
- Data reporting: Requires reporting of data on prior authorization to an authority such as the state.

Appendix A provides examples of state legislation relevant to Medicaid prior authorization reform (AMA 2024a).

## Conclusion

There is evidence that prior authorization reduces health care spending for specific services, items, and medications. It has been used successfully to reduce overutilization of some items, and to redirect care to less expensive treatments. Prior authorization can also help ensure that care aligns with accepted clinical standards by not covering experimental treatments or non-approved uses of medications.

However, prior authorization may cause delays or denials of needed care that contribute to adverse patient outcomes. Moreover, the prior authorization process can be burdensome and costly to providers and diverts clinical resources away from patient care. The process may also be burdensome to patients and caregivers when they have to devote time and effort to get approval for the care their provider has recommended.

These concerns have driven efforts to improve the prior authorization process to protect patients and reduce burden. At the federal level, the CMS Interoperability and Prior Authorization final rule focuses on improving the efficiency of the prior authorization process by requiring Medicaid and other payers to implement and maintain electronic prior authorization; by shortening the time frames in which prior authorization decisions must be made; and by increasing transparency in the information that is made available to patients, providers, and the public. In addition, some states have passed legislation to streamline the prior authorization process, require standards for developing the clinical criteria to determine medical necessity for requested services, improve transparency of prior authorization requirements, and require reporting to state authorities. New reporting requirements will expand our understanding of prior authorization's impact in Medicaid; however, some stakeholders have recommended more detailed reporting on approval and denial rates for specific types of services.

#### **Endnotes**

- <sup>1</sup> There is not an exact standard for medical necessity and it can vary by payer and plan, but definitions typically include language that care must (1) be "necessary and appropriate for the diagnosis, treatment, cure, or relief of a health condition," and (2) align with generally accepted standards of medical care (NAIC 2023).
- <sup>2</sup> This study included all 39 FFS programs and 266 active MCOs in 38 states and the District of Columbia.
- <sup>3</sup> The specific parity requirements for Medicaid MCOs regarding utilization management and treatment limitations are detailed in 42 CFR § 438.910.
- <sup>4</sup> States and payers may add drug coverage and prior authorization requirements to the APIs described in the rule. A proposed rule to reform the prior authorization process for drugs for MA and QHPs is currently listed on the unified agenda (OMB 2024).
- <sup>5</sup> These metrics include:
- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests, aggregated for all items and services, that (1) were approved, (2) were denied, (3) were approved after appeal, and (4) were approved after the time frame for review was extended.
- The percentage of expedited prior authorization requests, aggregated for all items and services, that (1) were approved and (2) were denied.
- The average and median time that elapsed between the submission of a request and a determination by the payer for (1) standard prior authorizations, aggregated for all items and services, and (2) expedited prior authorizations, aggregated for all items and services (CMS 2024a).
- <sup>6</sup> CMS defines an API as "a set of commands, functions, protocols, or tools published by one software developer ("A") that enables other software developers to create programs (applications or "apps") 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)" (CMS 2024a).
- <sup>7</sup> In a 2016 rule, CMS applied the prior authorization standards for prescription drugs for Medicaid FFS detailed in § 1927(d) to Medicaid MCOs (CMS 2016b).
- <sup>8</sup> CMS applied prior authorization demonstrations to the following items and services in select states: (1) repetitive scheduled non-emergency ambulance services (nine states), (2) non-emergency hyperbaric oxygen therapy (three states), (3) home health services (one state), and iv) power mobility devices (19 states). CMS also established a permanent prior authorization program for certain durable medical equipment, prosthetics, orthotics, and supplies in 2015 (GAO 2018).
- <sup>9</sup> In Michigan, although the policy change was associated with immediate cost savings, there was no significant difference in longer-term spending trends (Lu et al. 2011).
- <sup>10</sup> All states and the District of Columbia include prescription drugs as a benefit under the Medicaid Drug Rebate Program, authorized by Section 1927 of the Act. This program is a collaborative effort between federal and state governments and drug manufacturers. It offers substantial rebates to Medicaid programs to counterbalance prescription drug costs.
- <sup>11</sup> PDLs must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the governor of the state (§ 1927(d)(4)(A) of the Act).
- <sup>12</sup> As of February 2024, 28 states had removed Medicaid prior authorization requirements for hepatitis C virus treatment (CHLPI & NVHR 2024).
- <sup>13</sup> The U.S. Census Bureau definitions were used to assign states into regions. The states in the Northeast region included: Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont. The

South region included: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.

<sup>14</sup> These states are Iowa, Illinois, Louisiana, Maryland, North Carolina, New Hampshire, Ohio, Virginia, and West Virginia (in addition to the District of Columbia).

<sup>15</sup> These services are inpatient and outpatient surgery, inpatient and outpatient mental health and substance use disorder treatment, diabetes supplies and equipment, DME, and prescription drugs.

<sup>16</sup> Nine states and the District of Columbia passed prior authorization laws in 2023, and over 90 prior authorization bills were introduced in legislatures spanning 30 states in the first three months of 2024 (Henry 2024).

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# **Appendix A. State Examples of Medicaid Prior Authorization Reform Efforts**

TABLE A-1. Strategies and State Examples for Improving Prior Authorization in Medicaid as of March 2024

	State Examples	
Strategy	State	Summary
Gold Carding: Exempts a provider temporarily from prior authorization requirements for a certain medication or service when the provider achieves a specified percentage of prior authorization approvals for the given medication or service within a fixed time period.	AR	Providers with a 90 percent prior authorization approval rate for a service in a set six-month window in 2022 are exempt from prior authorizations for that service from January 1, 2024, to September 30, 2024. Plans can rescind gold cards if use increases by 25 percent (AR Code § 23-99-1120 2024).  Applies to Medicaid (AR Code § 23-99-1103 2024). MCOs can gain exemption from requirements by creating a plan to reduce or limit prior authorizations. If a plan is not submitted or approved, the MCO is subject to requirements beginning January 1, 2025 (AR Code § 23-99-1127 2024).
	wv	When a provider performs a service an average of 30 times per year within a six-month period and 90 percent of prior authorizations are approved, the provider is exempt from prior authorization for the service from that plan for six months. Subject to internal audit by plan (WV Code § 33-25A-8s 2022).  Applies to MCOs (WV Code § 33-25A-2 2022).
Electronic Prior Authorization: Requires that plans implement automated electronic prior authorization systems or electronic portals as an alternative to traditional prior authorization mediums.	WA	Plans must build and maintain an API with HL7 standards for services (by 2026) and drugs (by 2027) that allows providers to check on whether prior authorization is required, request prior authorization, and receive prior authorization decisions (WA Rev. Code § 48.43.830 2023). Applies to health carriers and their contracted entities (WA Rev. Code § 48.43.005 2023).
Exceptions: Exempts certain medications or services from prior authorization requirements.	KY	Plans cannot require prior authorization for births or initiation of neonatal intensive care services (KY Rev. Stat. § 304.17A-603 2023).  Applies to Medicaid FFS and MCOs (KY Rev. Stat. § 304.17A-005 2023).
	DC	Plans cannot require prior authorization for medication- assisted treatment for OUD, emergency services, or pre- hospital transportation (DC Code § 31–3875.02 2024). Applies to Medicaid (DC Code § 31–3875.01 2024).

	State Examples	
Strategy	State	Summary
Shortened Decision Timelines: Requires plans to issue prior authorization decisions sooner than federally established timelines.	ID	Requires a response to prior authorization requests for non-emergency services within two business days of receiving the medical information needed to make the decision. Exceptions to the timeline may be allowed in certain circumstances (ID Code § 41-3930 2023).  Applies to MCOs (ID Code § 41-3903 2023).
Limits on Retrospective Denials: Limits denials of payment after the medication or service was provided.	AK	Prior authorization for medically necessary care cannot be retroactively denied unless the approval was based on incomplete or inaccurate information (AK Stat. § 21.07.020 2023).  Applies to all health care insurance policies (AK Stat § 21.54.500 2023).
Clinical Criteria: Sets standards for developing the clinical criteria informing prior authorization decisions.	NE	Requires plans to use clinical criteria based on clinical evidence for prior authorization, and these criteria must be periodically evaluated. Allows plans to develop internal clinical criteria or purchase/license clinical criteria from qualified third party vendors (NE Code § 44-5426 2023). Applies to all health carriers (excludes workers' compensation insurance, risk management pool, and self-insured employers contracting with certain managed care plans) (NE Code § 44-5418 2023).
	LA	Requires health insurance issuers to document that their prior authorization programs use evidence-based clinical review criteria and have a plan for reviewing and updating these criteria (LA Rev. Stat. § 22:1260.42 2023).  Applies to Medicaid (LA Rev. Stat. § 22:1019.1 2018).  Does not apply to entities that provide limited scope dental or vision benefits (LA Rev. Stat. § 22:1260.41 2023).
Prior Authorization Reviewer Requirements: Requires that adverse prior authorization decisions or appeal decisions must be made by people with specific license requirements or clinical training, and/or people who do not have a financial incentive.	DC	Prior authorization denial decisions can be made only by physicians licensed to practice in DC, MD, or VA in the same or a similar specialty. Appeals must be reviewed by similarly licensed providers who have practiced in the same or similar specialty for at least five years (DC Code § 31–3875.06 2024).  Applies to Medicaid (DC Code § 31–3875.01 2024).
	GA	Prior authorization appeals must be reviewed by an actively practicing physician who is in the same or similar specialty and has experience providing the service being appealed (GA Code § 33-46-22 2022).  Applies to Medicaid (GA Code § 33-46-4 2022).

	State Examples	
Strategy	State	Summary
Transparency of Requirements: Requires payers to publish their prior authorization requirements and to provide the clinical basis for prior authorization decisions to the provider.	GA	Clinical criteria supporting the prior authorization decision must be shared with the provider at the time of decision. Insurers must make prior authorization requirements available on their website (GA Code § 33-46-20 2022).  Applies to Medicaid (GA Code § 33-46-4 2022).
Data Reporting: Requires reporting of data on prior authorization to an authority such as the state.	LA	The Louisiana Department of Health must submit an annual report on Medicaid managed care to the senate and house committees on health and welfare that includes information about prior authorization requests (both regular and expedited) and denials (LA Rev. Stat. § 40:1253.2 2018).  Applies to Medicaid managed care and any managed care plan providing dental benefits to Medicaid beneficiaries (LA Rev. Stat. § 40:1253.2 2018).