

Paths Forward on Prior Authorization: Exploring Reforms in California

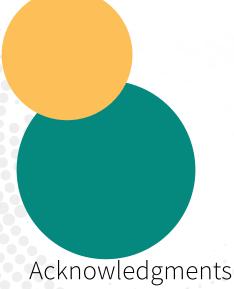
A NEHI Report

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About NEHI

NEHI is a member-driven, non-profit, unbiased organization. Its members include providers, hospitals and health systems, pharmaceutical and biotech companies, medical device, and technology providers, as well as associations and consultants. Through interdisciplinary collaboration and with our members' guidance, we research and examine tough and timely health care innovation issues from multiple, often divergent, perspectives. We then address policy and adoption challenges to promote the value of innovative products and processes.



Executive Summary

Prior authorization (PA) is a common form of utilization management (UM) used by commercial and public payers. It is a process that determines whether a health insurance entity will cover a prescribed product or service before it is provided to a patient. The process to obtain authorization can, however, be complex and confusing, given that the process and the application of PA differ across health care products, payers, and contracts. By way of understatement, variation in the PA process is a significant issue.

This report is part of a project funded by the California Health Care Foundation (CHCF) to produce feasible recommendations on ways to pursue reforms of PA in California. The report is the first step in this work, providing a baseline understanding of PA and reforms that have been implemented as well as those being considered in California and elsewhere. It includes: 1) existing information on the California healthcare market and PA practices; 2) a summary on the efficacy of and issues surrounding PA; and 3) a discussion of PA reform proposals over the last decade, comprising initiatives at the federal and state levels, including public policy- and industry-led approaches.

There is limited data available on PA use and application in California. A recent study provides helpful background and survey data on PA practices pursued by commercial plans representing approximately 40% of covered lives in California. Its findings demonstrate alignment on considerations in applying PA, while highlighting the intense variation in how PA is applied in practice.

Formal studies of the PA process, which we review, continue to provide support for payers' use of PA – to ensure that care provided is evidence-based and safe, to avoid certain types of misuse or overutilization and unnecessary spending, and to reduce healthcare costs. Much of the quantitative data supporting these themes derive from the application of PA to pharmacotherapies.

A significant part of both peer-reviewed and trade publications is, however, devoted to concerns surrounding the PA process. In certain circumstances (e.g., continuous courses of pharmacotherapy and behavioral health services), PA can lead to care delays or even avoidance. There is also documentation on the resources required to submit PA requests, adding to physician burden and administrative costs, for both payers and

providers. Recent reports make the case that the extensive resources required to submit PAs can also drive health inequities in care settings with fewer resources available to devote to PA than larger health systems.

Although the debate about PA is longstanding, efforts to reform the PA process have accelerated at both the federal and state levels. We describe and categorize federal, state, and voluntary reforms in three categories:

- Reforms capable of improving the PA process;
- Reforms that serve to establish trust within the PA process and boost its integrity;
- Reforms based on both provider and system performance.

At the federal level, Congress and CMS have primarily issued mandates that require certain public payers to establish an electronic PA (ePA) or automated PA process for prescription drugs and medical services. In addition, Congress is considering legislation that would gold-card eligible Medicare Advantage providers (i.e., exempt them from the PA process) for certain items and services.

States are largely working to standardize the PA process by establishing ePA standards, though momentum is growing to establish requirements that ensure consumers' continuity of care, timely decisions, and in rarer cases, use of standard medical necessity criteria. In seeking to reduce PA, five states have mandated gold-carding programs and states continue to introduce this legislation, though implementation challenges exist.

California is well into the fray and has enacted several laws over the last decade aimed at streamlining the PA process, particularly around prescription drugs and behavioral health services. The state requires payers to use a standard form for prescription drug PAs and uniform medical necessity criteria established by nonprofit professional societies for behavioral health services. California is also considering bills on automation and gold-carding providers for most medical and prescription benefits. Most notably, because of the penetration of risk-based contracts in California, some payers have removed PA for certain services included in capitated arrangements. It is difficult to determine the extent to which these arrangements have affected the number of PAs required in the state in comparison to other jurisdictions.

In the face of both provider complaints and active legislative proposals, major payers are voluntarily developing and testing PA reforms that streamline the process and reward providers and systems for their performance. There are several advancements in automation and artificial intelligence. In addition, several payers are choosing to remove PA requirements; their reasons for doing so are not clear or uniform. Likewise, the impact of risk-based arrangements on the prevalence and application of PA is not well documented, although it is assumed that such arrangements are decreasing PA requirements. Additional efforts to reduce administrative costs and burden could provide alternatives to PA, including issuing provider feedback on prescribing patterns on a normative scale and a statewide clinical utilization review board that evaluates and recommends medical necessity and PA requirements (among other UM functions) for select items and services or service areas.

In providing baseline information, this report highlights difficulties in defining the size and scope of the issues that affect providers, payers, and consumers in connection with the PA process. As noted, this is a first step in determining how to improve PA. The application of potential reforms requires an understanding of the issues they will resolve, the scope of their reach, and the potential added burdens they may instill. Further data and input from stakeholders are necessary. Our project seeks to gain that input to recommend reforms that will have a clear and cost-effective impact.

Context

Both commercial and public payers (we use the term *payer* to include health plans and insurers [unless otherwise specified] as well as Medicare and Medicaid) implement various strategies to ensure patient safety, decrease utilization of low-value care, reduce medical and pharmacy costs, and ensure care is "medically necessary" and delivered in the most appropriate setting. This practice is often referred to as utilization management (UM). One common form of UM is prior authorization (PA), which requires providers to obtain approval from a payer before delivering a certain service or product to patients. This process is also intended to ensure that the provider will be reimbursed for the services provided (under certain payer contracts). Prior authorization requirements have grown over the past several years with increasing health care costs and the introduction of new treatments and technologies. This trend, together with significant variation among payers in their application of PA, has generated insistent calls for reform of the process to address administrative costs and burdens.

The California Health Care Foundation (CHCF) has engaged the Network for Excellence in Healthcare Innovation (NEHI) to make actionable and pragmatic recommendations on ways to pursue state-wide PA reform efforts, given both common and disparate stakeholder priorities. To develop recommendations and understand the potential impact such recommendations would have, as well as to assess resource requirements, it is critical to outline and size the issues related to PA. This process includes obtaining an understanding of the California (CA) healthcare environment, the various methods in which PA is applied and processed throughout the state, the current laws and regulations aimed at streamlining PA in CA, and the opportunities for PA reform, given challenges consumers (we use the terms consumers and patients interchangeably), providers, and payers currently face.

NEHI will supplement this report throughout the project to include new and relevant data. We include in this report:

- Background on the CA healthcare market and PA practices;
- A literature scan on PA's utility and issues;
- A discussion of the last 10 years of major PA reform proposals at the federal and state levels, including both public policy- and industry-led approaches.

^{*} CHCF is scheduled to release survey data within the next several months that describe PA application and usage in CA.

Healthcare in California

Potential reforms of PA must be considered against CA's complicated mix of healthcare products, contracts, and payers, which are made even more unique by the fact that payers are regulated under two separate state departments. The Department of Managed Health Care (DMHC) primarily oversees* (2) Health Maintenance Organizations (HMOs) and other managed care plans. The California Department of Insurance (CDI) oversees "traditional" insurance policies. California's Department of Health Care Services (DHCS) administers the state's Medicaid program, Medi-Cal, and the Medi-Cal Access Program (MCAP); DMHC also regulates Medi-Cal Managed Care plans. To the extent not pre-empted by federal regulations, Medicare supplemental coverage and Medicare Part D standalone insurance plans are regulated under CDI. Finally, self-insured plans, issued principally by large employers and administered by commercial insurers under service contracts, follow the Federal Employee Retirement Income Security Act of 1974 (ERISA) and are regulated by the U.S. Department of Labor, Employee Benefits Security Administration (EBSA).

Data showcasing 2021 enrollment breakdowns[‡] indicate that 14.1 million consumers were enrolled in commercial plans (primarily large-group [9.5 million], small-group [2.3 million], or individual [2.3 million]), and that 14.7 million consumers were enrolled in public plans (11.8 million in Medi-Cal Managed Care, 2.9 million in Medicare Managed Care).⁵ An additional 5.5 million were enrolled in Administrative Services Only (ASO) plans (also known as third-party administrator plans) and are subject to ERISA regulation.⁵

^{*} The Department of Managed Health Care regulates two Preferred Provider Organizations (PPO) products from Blue Shield of California and Anthem Blue Cross.²

[†] Uninsured pregnant women who are considered "middle-income" are eligible for this low-cost health insurance program.³

[†] These breakdowns include only enrollment numbers under insurers regulated by DMHC and CDI.

Kaiser* (6) Foundation Health Plan is the largest insurer in CA with 8.5 million enrollees in 2021, spanning large-group, small-group, and Medicare plans. Anthem (Blue Cross), which offers both HMO and PPO products, is the second largest insurer (5.5 million enrollees in 2021), covering mainly ASO, large-group, and Medi-Cal plans. See Figure 1 for additional 2021 Enrollment by Insurer and Market information.

HMO products dominate the CA healthcare market. HMO enrollees must usually obtain care from an association of clinicians and hospitals that contract with the health plan, generally on a capitated or partially capitated basis.⁷ Both commercial and Medi-Cal plans primarily offer HMO products. On the commercial side, 2021 enrollment data

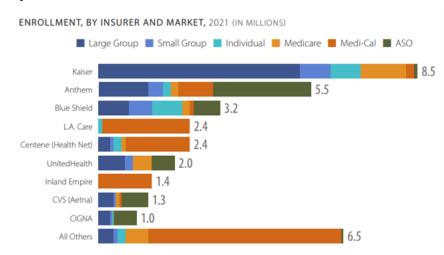


Figure 1. Retrieved from "2022 Edition - California Health Insurers, Enrollment," by Katherine Wilson. 2022. https://www.chcf.org/publication/2022-edition-california-health-insurers-enrollment/

showed that 10.8 million individuals were enrolled in HMO[†] products, the vast majority of whom were insured by Kaiser.⁵

Due to the different types of relationships and contracts, especially risk-bearing contracts, between payers and providers (hospitals and health systems, medical groups, and independent practice associations [IPAs]), PA functions are applied in different ways.⁸ While providers in risk-based arrangements (budget-based or capitated/partially capitated) often assume responsibility for PA,[†] the degree to which UM/PA functions are delegated or managed varies in association with the amount of risk they have assumed;⁹ health plans generally do not delegate UM for services to providers who have not assumed financial responsibility for them. Because a single Risk-Based Organization (RBO) may have multiple health plan contracts with different risk terms, a service for a patient insured by one plan may not require PA whereas the same service provided to a patient insured by a different plan may be subject to the PA process. Since

^{*} Kaiser Permanente comprises three entities: the insurance arm, Kaiser Foundation Health Plan, Inc., the regional Permanente Medical Groups, and Kaiser Foundation hospitals.⁶

[†] An additional 2.9 million were enrolled in PPOs, and a remaining 0.4 million in POS or other products.

[†] This is often referred to as a delegated care model.

information about contract provisions that define which party is financially responsible for providing specific services (DoFR) is not generally available, quantifying the amount of variation that exists or its impact is difficult.

This also makes sizing the scope of PA very challenging. The California Health Benefits Review Program's (CHBRP) October 2023 report on PA in California provides some further information based on survey responses from plans representing 73% of the commercial enrollees with health insurance that can be subject to state benefit mandates (approximately 13.4 million enrollees or some 40% of total enrollees). CHBRP reported that just over half (52%) of the enrollees in responding plans have health insurance in which no risk is delegated, 20% have health insurance that delegates between 51-100% of their risk to a risk-bearing organization (with only 2% delegating more than 76% of risk), and the remainder have unknown risk arrangements. Nevertheless, among the enrollees represented, 100% have plans that require PA for select items and services under their medical benefit, and 48% of enrollees are enrolled in plans that require PA for select treatments under their pharmacy benefit.

We discuss CHBRP's survey results further below and have supplemented our literature review with relevant citations from the CHBRP report. The report is worth reading. Perhaps mastering understatement, the report concludes that "there is a need for continued work to increase the efficiency and transparency of the [PA] process, and increase standardization across markets, payers, and health plans."

Prior Authorization and Its Application in California

CHBRP reported that its survey indicated four principal reasons that responding payers provided for implementing PA: improving patient safety and health outcomes, reducing unnecessary care, ensuring continuity of care, and cost containment. We review the data below.

^{*} The Assembly and Senate Committees on Health asked CHBRP to provide an overview of PA in CA, including the number and types of tests, services, and treatment[s] that are subject to PA, the health care services for which PA is most frequently requested; trends in approvals, modifications, denials, appeals, overturns, average length of time, etc.; and evidence of impacts of PA on patient outcomes and timely access to care.⁸ Survey respondents did not represent enrollees in the California Public Employees' Retirement System (CalPERS) or Medi-Cal managed care plans regulated by DMHC.

Services Subject to Prior Authorization

Based on its survey, CHBRP reported that between 5% and 15% of all covered medical services were subject to PA requirements, representing a wide range of total medical expenditures (7%-23%) and a slightly smaller variation in utilization (5%-12%). The report estimated that PA applied to between 16%-25% of pharmaceuticals but it did not provide expenditure or utilization data. By way of some explanation, the report stated that "responses on trends related to [PA] requests show high variability among health plans/insurers...due to a number of factors," including variation in risk delegation, market segments, medical practice, adherence to evidence-based treatment, and benefit design, among others. Plans and insurers reported that their medical-based guidelines for PA were generally publicly available for the items and services requiring PA.

The CHBRP survey yielded a list of services and pharmaceuticals most frequently requested that are subject to PA. It includes 30 medical services, which are listed in the order reported by health plans, but without quantification. CHBRP concluded that the most frequently requested services were not necessarily the most expensive categories of treatments, commenting that they were often the services requiring ongoing care (e.g., behavioral and mental health services, as well as physical, occupational, and speech therapies). Further,[†] the report highlighted that the frequency of requests varied significantly among plans: "... [V] arious imaging services comprised nearly all of one responder's most frequently requested services for [PA], and they were not listed at all for other respondents." The same observation held true for the application of PA to pharmaceuticals.

^{*} It is generally true that providers assume responsibility for UM activities, which may include PA, when they take on financial risk for services. The variation among health plans as to which tests, treatments, and services are subject to risk varies significantly (see Appendix B within the CHBRP report), making it almost impossible to draw conclusions about the amount of PA retained by health plans and imposed on providers in the significant market segment that HMO contracts constitute.

[†] Durable medical equipment (DME), imaging, genetic testing, and several referrals for a variety of services were in the top half of most frequently requested services. Plans reported that these service areas were among those for which PA most often failed to meet medical guidelines. Again, however, there was little overlap across plans.⁸

Prior Authorization Processes

This significant variation in PA requirements among plans stands in contrast to their reported processes for determining whether to apply PA; CHBRP found commonality there. In determining which items and services should be subject to PA, health plans and insurers generally reported using internal working groups to generate decisions.⁸ Areas of consideration were, however, broad, which helps explain some of the noted variation, including utilization rates, cost, availability of clinically sound alternatives, and administrative burden, among others.⁸ Payers who responded also noted that they reviewed their lists of items and services subject to PA.⁶ (10), (11) at least once annually, with the implication that this review led to ongoing changes in those services subject to PA.⁸ CHBRP noted that payers mentioned safety issues, "overutilization," and cost among the principal considerations in whether to associate PA with a service code. The frequency with which health plans conducted reviews, however, varied, as did the rate at which they made changes and the reasons for those changes.⁸

It is not clear whether payers considered the rate of approval for services subject to PA in determining whether to remove or change the application of PA. CHBRP noted that "the information received on denials, appeals, and resulting follow-ups was limited," and that approval rates† for medical versus pharmacy benefits were quite different—both initially and after providers submitted additional information requested by the plans. It was also not clear what percentage of PA requests were abandoned by providers after an initial denial, an issue that has several implications that we discuss later. The survey, however, provided the length of time to decision. The average length of time for a single electronic PA (ePA)‡ request for a medical benefit in 2022 ranged from a reported 12-46 hours. A single manual PA request ranged from 100-120 hours.8

^{*} AHIP's 2022 survey reflects this. ¹⁰ In addition, NEHI reported similar findings in its 2021 project, 'Streamlining Prior Authorization,' which convened providers, hospital systems, payers, and consumer advocates to discuss recommendations to improve aspects of the PA process in Massachusetts. In discussions with Massachusetts payers, it was revealed that payers regularly review their PA criteria and use standardized criteria, such as those by InterQual and MCG, for approximately 75% of their criteria. Providers, however, still expressed frustration with the remaining variation in PA criteria.

[†] Rates of approval under the medical benefits were higher than pharmacy benefits.8

[‡] The CHBRP does not define ePA in the context of their survey or larger report.

In contrast, the average length of time for a single ePA request in 2022 for a pharmacy benefit ranged from 31-69 hours, compared to a single manual PA request, which ranged from 30.5-55 hours.⁸

Payers reported that most authorization approvals are valid for approximately six months, although the range in responses was large (from 4-24 months).*

Conclusion

Like CHBRP, we viewed the survey as providing limited data, especially regarding "the use of [PA] impacts on care and prevalence." The amount of variation among payer policies and practices was evident: it is significant and challenges efforts to identify reforms with broad impacts.

Methods: Our Literature Scan

We performed a literature search through PubMed and OVID databases and the Internet, using search terms "prior authorization," "utilization management," "step therapy," and "prior authorization AND reform." Sources in this review include peer-reviewed articles, trade publications (articles and reports conducted by organizations or the government), and state and federal legislation. We excluded discussion of all non-U.S.-based publications and federal, state, and voluntary PA reforms published prior to 2013.

Prior Authorization Proccess and Purpose

As referenced above, PA, also referred to as *pre-certification*, *prior approval*, *prior notification*, *prospective review*, and *prior review*, is a process intended to determine whether a health insurance entity will cover a prescribed product or service before it is provided to a patient. Prior authorization is one example of a range of evidence-based medical management tools adopted by government programs like Medicare and Medicaid, as well as commercial payers, with the goal of ensuring that patients

^{*} It is unclear (though unlikely) whether the length in which PAs remain valid also applies to beneficiaries who payers.⁸

receive optimal care based on well-established evidence of efficacy and safety. Payers' will verify that the patient's plan covers the service requested, and that the service requested is medically necessary. Medically necessary care is generally defined as health care services that are needed to diagnose or treat an illness, injury, condition, disease, or its symptoms, and that meet the standards of good medical practice in the local area; what falls into the category of medical necessity can be a matter of debate and contention between payers, providers, and patients. In addition, payers may evaluate provider network restrictions and site of service.

There are other UM practices implemented by payers to achieve similar goals to that of PA which we include and exclude for the purposes of this report. For example, step therapy (which we include in this report as a form of PA), is used to coordinate care for patients who must undergo several classes of drugs or therapies prior to approval for a higher-cost or more experimental treatment.¹⁴ We do not include, however, financial forms of UM, such as formulary restrictions and cost-sharing.

As illustrated in CHBRP's survey, PA requirements vary based on the payer providing coverage for the service. The processes, however, generally follow the same protocol.¹⁵

- 1. The provider assesses the patient and recommends a health care service;
- 2. Before ordering the service, the provider (the term *provider* may include clinicians, physicians, or non-clinical staff) must determine whether the patient's plan requires PA for the service. If so, the provider must submit information on the patient to the payer;
- 3. Depending on the level of automation available and the prescribed service, the payer's administrative or clinical staff review the PA request and verify coverage for the service and its medical necessity. The information used for medical necessity criteria often includes the patient's current medical conditions, medications, and medical history. "Medical necessity" is the broadest and most common use of PA and applies to medical services, some of which include surgeries and imaging studies, as well as pharmaceuticals.¹³

^{*} Payers often delegate PA to external vendors. The use of the term "payer" here can refer either to the payer itself or its delegated PA/UM vendor.

[†] This internal control is applied to ensure patients receive in-network services and are not faced with unexpected and costly medical bills. The criterion for approval is therefore based on the patient's health plan product.

[‡] For example, PA may be required before scheduling a surgery within a hospital rather than an alternative site of care, such as an ambulatory surgery center, as ambulatory surgery centers are generally less expensive sites of service.

- The service will be approved if the patient's circumstances match the criteria used for authorization;
- The service will be denied if the patient's circumstances do not match the criteria used for authorization. At this point, the provider and/or the member may go through a pre-determined appeals process.*

PAs are often submitted manually^{†, (16)} (e.g., via facsimile or telephone) by providers or providers' staff to the payer, making the PA process and decisions time-and resource-intensive. Concerns surrounding the process have led to the availability and uptake of electronic prior authorization (ePA) and automation which we describe further under *History of Reform and Current Landscape*.

Prior Authorization Benefits

America's Health Insurance Plans' (AHIP) 2019 survey among commercial payers[‡] cited the top priorities of their members' PA programs, which echoed statements in the literature on the stated purposes of PA.§ Ninety-eight percent of surveyed payers report that their PA programs aim to improve quality/promote evidence-based care, 91% report they protect patient safety, 84% report programs address areas prone to misuse, and 79% report they reduce unnecessary spending.¹⁷

CHBRP's report concluded, as we do, that data on the use of PA and its impacts on care were limited. Prior authorization denials may indicate the fulfillment of PA's purposes, but this is not always the case. As the CHBRP review noted, denials may reflect failures of documentation that, when corrected, result in service approvals.⁸ It is also difficult to quantify the impact of PA due to its interaction with other policies and practices.¹⁸ We discuss the available data on PA benefits below.

^{*} Clinicians on both the payer and provider side generally become involved in the determination of medical necessity but may also participate in decisions regarding site of care or alternative services if the patient encounters benefit limits.

[†] The Council for Affordable Quality Healthcare (CAQH) reported that approximately 33% of submissions are fully manual.¹⁶

[‡] AHIP surveyed 44 commercial health plans covering approximately 109 million individuals.

[§] The CHBRP report noted the similarity between AHIP's survey findings and its own on this point.8

Driver of Evidence-based Care

An example of PA's impact in ensuring that patients receive only evidence-based care is shown through the use of pre-approval in antibiotic prescribing. ^{19, 20, 21} Prior authorization is an effective tool in Antimicrobial Stewardship Programs. An academic medical center in Ohio expanded its Antimicrobial Stewardship Program and required PA for specific antimicrobials. The program reduced utilization of certain antimicrobials with an annual cost savings of \$61,000 (though it is not clear what percentage of cost this constituted), without negatively affecting outcomes. ²¹ Program data also showed that patient outcomes improved (i.e., less time spent on mechanical ventilation, shorter length of stay, etc.), although these findings were not statistically significant. ²¹

Payers also apply PA when there is variation among providers in following evidence-based care guidelines. Prior authorization for oncology treatments may be justified on this ground. A study by Newcomer et al.²² concluded that a private payer that implemented a PA tool using a clinical decision support mechanism (CDSM) for chemotherapy drugs saved over \$5 million in the span of one year. The tool assessed patient drug interactions and provided real-time therapy alternatives. Payers often emphasize the point that evidence-based treatments may be less expensive than treatment alternatives.

Impact on Patient Safety*

A common example of PA's contribution to patient safety is through its use to flag potentially dangerous drugs, especially opioids. We identified one study that examined methadone prescribing practices and methadone overdoses among Medicaid enrollees in three states[†] and found an association between Medicaid preferred drug lists (PDLs) that require PAs for methadone and lower rates of methadone overdose among Medicaid enrollees.²³

^{*} See also the CHBRP report.8

[†] Florida, North Carolina, and South Carolina

Misuse and Spending

Prior authorization has been shown to materially lower misuse and spending among Medicare enrollees in certain contexts. The Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services (CMS) found that PA for regular, non-emergency ambulance transportation for Medicare beneficiaries reduced unnecessary use by more than 70%, lowering total Medicare spending by 2.4% without impacting quality of care or beneficiaries' access to care.²⁴

Costs

Studies showing cost reductions include the reduction of unnecessary and high-cost care in favor of less expensive options. ^{25, 26, 27} For example, in 2015, the American Enterprise Institute (AEI) for Public Policy Research examined the effect of prescription drug PAs on Medicare Part D net costs. AEI found that while approximately 4% of prescription drugs in Medicare Part D require PA, this constituted 20% of net drug spending. ²⁷ Furthermore, by applying PA, the Medicare Part D program was able to reduce the use of drugs subject to PA by 25% and overall Part D spending by 3%. ²⁷ AEI estimates that this reduction in spending is equivalent to \$95.88 per beneficiary-year. ²⁷ In 2018, the Government Accountability Office (GAO) recommended PA program expansion in both Medicaid and Medicare, citing benefits in reducing unnecessary care and associated costs. ²⁸ This expansion built upon a 2012 effort in which traditional feefor-service (FFS) Medicare placed PA on the use of power mobility devices (PMDs) ²⁹ in seven states with high rates of PMD fraud ³⁰ (i.e., PMDs were prescribed to patients who did not meet medical necessity criteria). These states saw monthly expenditures for PMDs drop from roughly \$12 million to \$3 million ²⁹ over approximately two years.

Prior Authorization Concerns

There is significant qualitative (especially physician and hospital survey) data on the "burdens" of PA,*,(31) although quantitative data, especially relating to cost, also exists.

^{*} Thirty-three percent of physicians surveyed in the 2022 AMA PA Physician Survey reported that PA has led to serious adverse patient effects.³¹

Delays in Treatment

Much of the literature highlights detrimental effects—particularly through delays in care—on patients engaged in continuous courses of pharmacotherapy. Drug regimens in mental and behavioral health services, when subject to PA, have been associated with disruptions in patient care.³² Delays in care were also found among rheumatology patients who were prescribed infusible medications.³³ According to one study, patients were more likely to experience a delay in treatment³³ (median 31 days, interquartile range 15-60 days) when the medication was subject to PA compared with patients prescribed the same medications without PA (median 27 days, interquartile range 13-41 days). Furthermore, when initial PAs were denied, patients were more likely to experience exposure to prednisone-equivalent glucocorticoids whose long-term use has been associated with adverse patient outcomes.³³

Prior authorization delays and barriers to treatment are also prevalent within behavioral health services. A 2023 Kaiser Family Foundation survey among adults with health insurance found that 26% of respondents who sought care or prescription drugs for a mental health condition in the past 12 months reported that their insurance denied or delayed PA approval. Peer-reviewed articles have produced similar findings, particularly around prescription drug access for behavioral health conditions. A study by Andrews et al. Used data from the National Drug Abuse Treatment System Survey in 2014 and 2017 to examine buprenorphine provision, which has been shown to reduce "opioid-related morbidity and mortality and the risk of relapse and overdose during recovery." The authors found that PAs for buprenorphine in Medicaid programs were associated with lower odds of buprenorphine pharmacotherapy within addiction treatment programs.

Physicians have protested that variation in PA requirements among payers and lack of transparency and trust in medical necessity criteria create administrative burden that also leads to delays in care.[†] Survey data from the 2022 American Medical Association

^{*} This was compared to 13% of respondents who did not seek care or prescription drugs for a mental health condition.

Providers may order a service or medication, unaware that the order itself is subject to PA until the imaging technician, scheduler, or pharmacist attempts to fulfill the order. This initiates a time-consuming back-and-forth exchange between the ordering provider and the service provider. Often, the service provider can submit the PA at this point, but some plans require the ordering provider to submit the PA. This action is referred to as retrospective PA.

(AMA) Prior Authorization Physician Survey³¹ showed that more than half (56%) of the providers reported that PA always or often delays access to necessary care. Additional responses indicated that some PA restrictions have led to treatment abandonment or even hospitalizations.*

Impact on Health Equity

Some groups have raised concerns about the impact that PA has on health disparities among underrepresented and underserved populations. The Association of Black Cardiologists (ABC) Prior Authorization Workgroup surveyed physicians (90% were cardiologists) and highlighted the significant burden associated with working in small and lower-resourced facilities, as the staff typically cannot devote time exclusively to PAs.³⁸ Sixty-four percent of respondents reported that they can only spare up to two hours per week to complete PAs.³⁸ Providers reported a disproportionately negative impact on underserved populations who rely on care from such facilities, both in terms of delays in care and provider-patient relationships.^{38,39} As discussed below, reforms that remove PAs based on approval rates may exacerbate PA's negative impact on populations treated by caregivers who do not have the resources to address initial denials with further documentation and explanation.

Because the application of PA may reflect regional biases, it may also widen disparities in access to treatment. A study by McManus et al.⁴⁰ theorized that assigning PA to pre-exposure prophylaxis (PrEP) for HIV reflected regional biases and would contribute to lower levels of PrEP uptake in the South, compared with other regions of the country. The authors examined whether PA was required for PrEP under qualified health plans (QHPs) in the Affordable Health Insurance Marketplace. Results indicated southern QHPs were nearly 16 times more likely to attach PA requests to PrEP than other regions.⁴⁰ Because there is also evidence that the South is home to higher rates of stigma related to the LGBTQ+ community, stigma related to HIV, and more laws criminalizing HIV than in other parts of the country,^{41,42,43,44} the authors suggest that the decision to apply PA in this instance may reflect stigma associated with treatment for conditions more prevalent among specific populations.⁴⁵ Other plan characteristics

^{*} Twenty-eight percent of providers surveyed reported that patients often or always abandon treatment associated with PA, and subsequently attributed treatment abandonment to patient harm and a decrease in quality of care, with 33% of physicians reporting that PA has led to a serious adverse event, and 25% of physicians reporting that the need for PA has led to a patient's hospitalization.³¹

did not account for this regional variation.⁴⁰ While the annual incidence of HIV cases is highest in the South, uptake of PrEP is lowest in this region.^{46, 47, 48, 49}

Administrative Burden and Cost

Thirty-five percent of physicians surveyed by the AMA state that they have staff who work exclusively on PAs, spending an average of 14 hours per week completing PA requests.³¹ The American Hospital Association (AHA)⁵⁰ produced a report in which they discuss administrative burden through the results of their surveys, conducted in 2019 and again from December 2021 - February 2022, providing anecdotal evidence of cost estimates by various hospital systems. The Council for Affordable Quality Healthcare (CAQH) Index reported an overall increase[†] in spending for payers and providers, though more than 85% of the spending is attributed to providers, bringing the estimated total spend for PA in 2022 to just over \$1 billion.¹⁶

Two recent studies also focused on costs associated with UM for pharmaceuticals though each use different methods and estimates to determine costs. The first generated a model to estimate annual costs[‡] of PA compared to the estimated cost savings PA derives. The model used conservative estimates (based on CAQH estimates) and found that despite the industry cost savings gained through the application of PA, PA still increases annual healthcare spending by \$1.9 billion. Using higher cost estimates from the literature, the authors suggest that PA can increase annual healthcare spending by as much as \$13.2 billion.

The second study took an expansive (or, depending on one's outlook, comprehensive view of annual drug UM costs.§ The study defined these as "direct" and "associated"

^{*} The AHA reported that a "20-hospital system spends \$17.5 million annually just complying with [PA] requirements" and that "a large, national system spends \$10 million per month in administrative costs associated with managing health plan contracts, including two to three full-time staff that do nothing but monitor plan bulletins for changes to the rules." ⁵⁰

[†] The report notes that "the medical industry spent more conducting [PAs over the course of the year] as higher utilization and lifted waivers [from COVID-19] increased the volume of [PAs]."¹⁶

[†] The authors' definition of "costs" includes all financial costs associated with PA (i.e., additional health care costs due to PA non-adherence, costs to providers, costs to employer-plans, and labor costs for Pharmacy Benefit Managers and insurers).

[§] The study was funded by Novartis Pharmaceuticals.

costs stemming from PA and financial systems (such as patient cost–sharing).⁵² It found that the amount exceeded \$93 billion, incurred by payers, providers, drug manufacturers, and patients.⁵² Costs incurred by patients, according to the study, were almost \$36 billion, followed by physician costs (\$26.7 billion). The study included costs incurred by pharmaceutical manufacturers at approximately \$24 billion, which counted the costs of programs that supported physicians and patients in navigating utilization management and the costs of meeting co-pay or co-insurance requirements or otherwise offering free medications through patient assistance programs.⁵² Payer costs were estimated at \$6 billion. Unlike the prior study, the authors do not estimate savings from PA processes, but suggest ways to mitigate—without eliminating—PA.*

Lack of Clarity

Providers assert³¹ that a contributing factor to their administrative burden is the lack of transparency in PA requirements[†] and medical necessity criteria. Not all payers are required to make their medical necessity criteria publicly available, although many do. Nevertheless, depending on the source of the rules (i.e., national standards, internal rules, or externally developed rules), it can be difficult to obtain clear instructions on what constitutes "medical necessity" for many items and services.

While many plans rely on national standards or adopt guidelines developed by professional societies, their internal processes can result in the adoption of proprietary medical necessity rules (like InterQual or MCG) as well as payer-specific guidelines.⁵³ A 2022 report published in the Iowa Law Review discusses the historic shift from health insurers' use of standards when designing medical necessity criteria, to a more complicated and specific rule-based method.[‡] The report notes that "public access to rules of medical necessity that are developed by third parties is significantly more

^{*} The authors provide suggestions to mitigate these costs, focusing especially on the need to promote "exchange of value-based pricing for value-based access," which, they note, would not—and should not—eliminate UM, as it will still have an important role in minimizing the use of inappropriate and over-priced medications.52 They advocate for additional studies to support movement in this direction.

¹ It is important to note that some payers are required to publish some PA requirements (e.g., services subject to PA) on their respective website. This does not facilitate an easy comparison of PA requirements across plans.

[‡] "Rules tend to define permissible conduct in advance, thereby leaving adjudicators limited discretion when applying those rules in particular cases. By contrast, standards typically entrust adjudicators with discretion to determine how a broad principle should be applied in individual circumstances."⁵³

limited than public access to insurer-specific rules of medical necessity. When state utilization review laws require such rules to be publicly available, guidelines purchased from private third parties are often exempted from such requirements."⁵³ Moreover, even when medical necessity criteria are relatively clear, providers still mistrust their validity. Recent survey data compiled by the AMA³¹ largely reflects provider uncertainty surrounding the determination process when designing medical necessity criteria.*

The variation in PA guidelines by state, patient plan products, and associated PA requirements (e.g., medical necessity criteria, submission criteria, and services subject to PA) across health plans also creates confusion, increasing the time providers need to determine the correct authorization process for a given patient. ^{54,55,56} One study also documented variation in the amount of burden among plans. Providers spend significantly more time processing commercial insurance PA requirements than Medicaid PA requests (PA took roughly 20 minutes to complete [beta = 20.017, p < .001]; Medicaid requests took 14 minutes [beta = -6.085, p < .001]). ⁵⁵

History of Reform and Current Landscape

Prior authorization has been a major target of reform for several years. In 2018, the AHA, AHIP, AMA, American Pharmacists Association (APhA), Blue Cross Blue Shield Association (BCBSA), and Medical Group Management Association (MGMA) convened to craft a consensus statement on the tenets[†] of PA reform.⁵⁷ Partially inspired by this effort, the AMA and other state medical societies have actively pursued the passage of bills that would regulate and eliminate PA. Below, we summarize and comment on both enacted and current legislative, administrative, and voluntary efforts. We primarily categorize these as: 1) reforms capable of improving the PA process; 2) reforms that

^{*} Perceptions surrounding evidence in the formulation of PA requirements vary across payers and providers. For example, AHIP's survey¹⁰ found that 100% of payers reported that the criteria used for PA is based on peer-reviewed, evidence-based studies; however, 31% of providers who responded to the AMA's survey reported that PA criteria is "rarely" or "never" based on evidence or guidelines from national medical specialty societies, and over 10% of surveyed providers reported that they do not know how PA criteria is determined.³¹

The group identified five major areas for improvement within PA programs and processes: selective application of PA (e.g., gold-carding programs or removing PA under risk-bearing arrangements); PA program review and volume adjustment (e.g., removing PA for services with high approval rates or low utilization rates); transparency and communication regarding PA; continuity of patient care; and automation to improve transparency and efficiency.

serve to establish trust within the PA process and boost its integrity; and 3) reforms based on both provider and system performance.

Our review looks first at federal activities, then at state actions, with a section on CA. We conclude with private sector initiatives. We also include a short section on new UM efforts that are adjacent to the PA process but that could be tested and applied instead of PA.

Federal Prior Authorization Efforts and Reforms

Federal legislative and administrative efforts have largely focused on changes that would improve the PA process by eliminating burden and improving access to care, particularly by promoting PA automation (which we define). There are also efforts that aim to remove PA requirements.

Improving the Prior Authorization Process

Electronic prior authorization and automation. Congress and CMS have been instrumental in driving ePA (and automation). "EPA" is an umbrella term referring to the electronic method through which providers and payers send requests and receive decisions, respectively, and one that generally refers to the use of a portal. ⁵⁸ "Automation" is a subset of ePA, but refers specifically to PA processes that utilize a defined set of data exchange standards that either minimize or avoid human intervention.

Several automation products on the market offer solutions to some or all segments of the PA process.⁵⁹ These are often directly integrated within a provider's EHR system.⁵⁸ Once the provider places an order, the solution extracts necessary medical information based on payers' medical necessity criteria, auto-populates the submission form, and sends the completed request to the payer.⁵⁸ Upon receipt of this information,^{* (60, 61)} in most circumstances, the payer's system is able to render an immediate response

^{*} There are multiple efforts to standardize data exchange between provider and payer systems. HIPAA-covered entities are required to use ASC X12 Version 5010 for specific electronic transactions (unless the organization is granted an exception), though this does not apply to retail pharmacies.⁶⁰ The Da Vinci Project also aims to create value in care coordination with the use of HL7's FHIR standards, which are similar to a guidebook for creating interoperable software for healthcare data exchange.⁶¹

without further personnel review. Although complicated services will require human review, there is consensus that automated PA reduces provider time (i.e., saves an average of 11 minutes when compared with manual PA transactions), ¹⁶ results in faster payer responses, ⁵⁸ reduces the number of unnecessary PAs, ⁵⁹ facilitates fewer delays in care, ⁶² and is more cost-effective than manual PA. Furthermore, automation will facilitate access to data measuring the PA process.

One of the earliest federal provisions on ePA is associated with the effort to address the inequitable application of PA to behavioral health services. (63) Congress passed H.R. 6, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment Act, (SUPPORT Act) in 2018. Section 6062 of the Act requires the Secretary of Health and Human Services (HHS) to establish a standard ePA format for PA requests submitted for drugs covered under Medicare Part D.

In 2020, CMS finalized a rule that implemented section 6062, which requires Medicare Part D prescription drug plans to support the NCPDP SCRIPT standard version 2017071 within their e-prescribing programs. ⁶⁵ Adoption of the CMS' NCPDP SCRIPT standard ⁶⁶ provides a prime example of the benefits of automation. By supporting this ePA standard, Part D providers can determine at the time of the order whether PA is required and can electronically submit the necessary documentation, thereby reducing time needed to fulfill the request and potential for delays in care. ⁶⁵ This type of reform has led to further PA automation and standardization requirement efforts across additional public plans, which we discuss below.

In December 2020, CMS also released a Proposed Rule that would require the use of Fast Healthcare Interoperability Resource (FHIR) Application Programming Interfaces (APIs) to automate non-pharmacy PAs. Citing payers' concerns over the speed at which the rule had been finalized, the Biden administration withdrew the rule.⁶⁷ The rule would have also mandated that payers review urgent PA requests within 72 hours,

^{*} The 2022 CAQH report on automation estimated that providers could spend approximately \$5 per automated PA, compared with nearly \$11 per traditional PA. ¹⁶ Furthermore, the CAQH Index estimates \$449 million in cost savings across the medical industry if PA was fully automated, although it is likely much of that savings will be diverted to other revenue cycle areas through personnel and other means.

[†] The Mental Health Parity and Addiction Equity Act63 was enacted in 2008 to ensure mental and behavioral health care services under commercial payers were not subject to stricter coverage and utilization standards than general care for other conditions.

and non-urgent PA requests within seven days. Additional requirements addressed transparency and insight into denied PAs as well as metrics on procedures that require PA.⁶⁷

Two years later (December 2022), however, CMS released a similar Proposed Rule titled 'Advancing Interoperability and Improving the Prior Authorization Process Proposed Rule (CMS-0057-P),' which would, among other provisions, require Medicare Advantage organizations, State Medicaid and Children's Health Insurance Program (CHIP) Fee For Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on Federally Facilitated Exchanges (FFEs) to build and maintain a FHIR Prior Authorization Requirements, Documentation, and Decision (PARDD) API to automate the PA process for providers through their EHRs.⁶⁸ The Proposed Rule would also increase PA policy and process transparency for all methods by which PA is submitted by requiring impacted payers to provide a specific reason for PA denials, report annual PA metrics,' and set time limits for PA decisions (for most payers, a 72-hour window to issue decisions for urgent PAs, and seven calendar days for non-urgent PAs).⁶⁸

While the rule has not been finalized, CMS advanced the rule to "pending review" on October 25, 2023. Historically, this status in the rule-making process signifies that the rule will be finalized in 90 days.

Congress is also focused on advancing ePA within the Medicare Advantage Program through the "Improving Seniors' Timely Access to Care Act," which was introduced during the 2019-2020 legislative session,⁶⁹ and is now part of the "Health Care Price Transparency Act of 2023" (H.R. 4822). It is being actively considered during the current session (118th Congress [2023-2024]).⁷⁰ The Act would:

- Require Medicare Advantage plans to establish an ePA process;[†]
- Direct HHS to require Medicare Advantage payers to provide real-time ePA

^{*} The rule would require impacted public payers to report a list of all items and services that require PA, the percentage of standard PAs approved, the percentage of expedited PAs approved, average and median time elapsed between the submission of a request and a determination by the payer, plan, or issuer for standard PAs, and more.

[†] If passed, this provision would precede the time limits for PA decisions outlined in the CMS Proposed Rule on automation.

- decisions* or remove PA from services with high approval rates;
- Require reporting transparency from Medicare Advantage plans regarding approval rates, denials, successful appeals, and turnaround times for PA requests.

The AMA and AHA, among other associations, support this legislation. They cite a major opportunity to reduce administrative burden by automating the PA process and requiring plans to provide real-time decisions.⁷¹

Despite its benefits, barriers to automation remain. First, interoperability must be established using standard implementation guidelines (e.g., FHIR-based standards as outlined in CMS's Proposed Rule). ⁶¹ While using standard implementation guidelines is not essential to automate, standardizing how provider and payer systems communicate is crucial to scaling automation. [†] (⁷²) Second, uptake of ePA is necessary to advance automation. The CAQH reported a fully electronic PA adoption rate of only 28% in 2022 across medical plans surveyed, reflecting low provider uptake. ¹⁶ Many providers cite doubts about the safekeeping of insurance information and other confidential patient information within EHR systems. ⁷³ Automation is unlikely to yield benefits until it is mandated. Finalization of the federal rule will be an important initial step, but broader adoption may require individual state action or assistance.

Removing prior authorization requirements. Federal rule-making and legislation have also addressed stakeholders' requests to ensure timely access to care by removing PA requirements. In 2023, CMS released the '2024 Medicare Advantage and Part D Final Rule (CMS-4201-F),' which, among other provisions, removes and clarifies PA requirements to avoid disruptions in enrollees' care. Its provisions include prohibiting a Medicare Advantage plan from requiring PA for a new member's active course of treatment for the first 90 days, requiring a PA to remain valid for a continuous course of treatment for as long as "medically reasonable and necessary to avoid disruptions in care," and requiring Medicare Advantage plans to form UM Committees to review their

^{* &}quot;In establishing the definition of a real-time decision... the Secretary shall take into account current medical practice, technology, health care industry standards, and other relevant information relating to how quickly a Medicare Advantage plan may provide responses with respect to prior authorization requests." It is likely that the defined response time would supersede response times as required in the CMS Proposed Rule (CMS-0057-P).

[†] The AHA produced recommendations in 2020 on the standardization of PA processes and requirements for payers and providers, which could be achieved through automation. To For example, recommendations call for improvements in data sharing by recommending standardized formats for provider submission forms and timely responses from payers.

PA policies on an annual basis and ensure such policies are consistent with Traditional (FFS) Medicare's national and local coverage decisions and guidelines.⁷⁴ It is likely that, in addition to claims review, CMS must rely on providers' and patients' reports of nonadherence to enforce these provisions.⁷⁵

Rewarding Provider and System Performance

Gold-carding. Payers use gold-carding to "reward" individual providers or provider groups within a health system by waiving PA or automatically approving PA requests for select services. ⁷⁶ Providers must demonstrate low denial rates (i.e., 3%-10%) or submit a lower than average number of PA requests. ^{58,77} Once enrolled in the program, providers typically maintain their gold-card status if they continue performing within the waiver's terms (e.g., for denials, ≥90% approval rate). According to AHIP's 2022 survey among commercial plans on Prior Authorization Practices and Gold-Carding Experiences, two-thirds of respondents reported that they review eligibility annually or semi-annually. ⁷⁷

Last summer, two House Representatives introduced a bi-partisan gold-carding bill (H.R. 4968). The bill, titled "Getting Over Lengthy Delays in Care As Required by Doctors Act of 2023" or the "GOLD CARD Act of 2023," would amend the Social Security Act to exempt Medicare Advantage providers from PA for one plan year for select items and services—though not Medicare Part D drugs—if they demonstrate a ≥90% PA approval rate during the previous plan year. 78 A provider must demonstrate a ≥90% PA approval within each Medicare Advantage plan with which they contract (e.g., a provider could be granted a PA exemption within one Medicare Advantage plan but not within another). The bill also requires the Secretary of HHS "to submit to Congress a report on the potential impacts of the amendment made by this section on communities at high risk for health disparities."⁷⁸ The bill remains in the House as of September 2023. Professional associations such as the AMA have praised the bill, claiming that the reform effort would "give physicians relief" from the burdensome PA process. 79 Payer concerns about implementing this exemption practice include the complexities of establishing eligibility criteria and performance audits, as well as the belief that providers will revert to utilization patterns that exceed the gold-carding program standards. The audit process is certainly viewed as burdensome for payers and providers alike. 11 There is also evidence suggesting that initial "good" performance displayed to achieve gold-card status typically ebbs once attained. 10,80,81

Gold carding may also create inequities among providers and their patients. Larger health systems have more time and resources to overcome initial denials and thereby improve their approval rates.⁵⁸

State Prior Authorization Efforts and Reforms*

In examining state legislative mandates and proposals, we referred to the AMA's 2022 Prior Authorization State Law Chart, which tracks states' PA legislation along 11 main criteria. These include criteria that, if implemented correctly and at scale, should improve the PA process, establish trust by increasing process transparency, and reward provider performance, such as through gold-carding. 82

Improving the Prior Authorization Process

Electronic prior authorization and automation. Thirty states have requirements in place that require a payer to make ePA submissions available in some format. For example, Michigan passed a law in 2022 that would standardize the PA submission process for certain medical services by requiring payers to develop and begin using an ePA solution starting in June 2023, among other provisions.⁸³ Finally, of the 30 states requiring ePA, the majority require electronic prescription drug transactions to follow NCPDP standards.

Overall, PA automation mandates do not appear prevalent across states. California recently signed a bill mandating automation in accordance with CMS's Proposed Rule, however, that bill was vetoed by the Governor.⁸⁴ We discuss this below. The Massachusetts Health Policy Commission, an independent state agency tasked with monitoring health care spending growth, recommends mandating automation at the state level.⁸⁵ Legislation mandating automation is expected to be introduced soon.

Ensuring continuity of care. Ten states have implemented restrictions that limit the number of PAs required for a course of care or extend the timeframe for which an initial PA remains valid. In Georgia, PAs for prescription drugs for patients with a chronic

^{*} State actions do not cover plans subject to the Employee Retirement Income Security Act (ERISA).

[†] Additional tracking criteria include ePA and use of standard forms, response times, retrospective denials, data reporting, clinical criteria and medical necessity, notice of new requirements, qualifications of reviewers, and peer-to-peer/appeal process and miscellaneous.

condition must remain valid for one year or until their last day of coverage—whichever comes first.⁸² In Illinois, medical or prescription drug PAs for patients must remain valid for six months; if the patient has a chronic condition, the PA must remain valid for 12 months.⁸² Finally, West Virginia only allows one PA per episode of care, otherwise known as proactive authorization.⁸²

There are also restrictions placed on state-mandated plans to honor PAs for new members for a limited amount of time. Plans in Georgia must honor new members' prior PAs (for medical and prescription drugs) for 30 days.⁸² Illinois requires plans to honor new members' prior PAs for 90 days.⁸²

Both reducing PA frequency and waiving PAs when a patient changes health plans address issues that consumers and providers have cited as significant irritants. We have not, however, seen evaluations that compare the cost and quality of care for conditions affected before and after the extended approvals.

Ensuring timely access to care. Thirty-four states have imposed requirements on commercial payers to respond to PAs in a timely manner. Most states differentiate between urgent and non-urgent response times. For example, payers in Alaska, Arkansas, Iowa, Kentucky, New Mexico, and Virginia must respond to urgent PAs within 24 hours with a decision or a request for more information. Four states allow payers to wait as many as 15 days to render a decision for non-urgent requests. Some states also differentiate response times for prescription drugs; these time frames vary widely. For example, payers in Maryland must respond to ePAs in real-time, however, Delaware payers must respond to ePAs within five business days.

States' public programs typically have separate PA response time requirements. For example, Massachusetts' Medicaid program, MassHealth, is required to respond to PA requests within two to three weeks, depending on the service. ⁸⁶ Commercial payers in Massachusetts, however, must respond to PAs within two business days. ⁸²

Pennsylvania's Medicaid and CHIP programs are required to respond to PAs within two business days. 82 Conversely, Pennsylvania commercial payers must respond to PAs within three days for urgent requests and 15 days for non-urgent requests. 82

^{*} Colorado, New Jersey, Pennsylvania, and Rhode Island

Removing prior authorization requirements by contract. We found a few examples of state Medicaid contracting terms that removed PA for certain services. Oklahoma's Medicaid program signed a value-based contract with a drug manufacturer in 2018 for a drug used to treat bacterial skin infections (oritavancin). Under this contract, oritavancin would become the first-line treatment option and no longer require PA. In return, the drug manufacturer would rebate the state if the state incurs higher than expected costs. Oritavancin is an expensive drug, however, usage should curb costs since it does not require hospitalization to administer, unlike similar, less expensive drug options. We could not locate findings as a result of this arrangement.

Vermont also participated in value-based contracting through its All-Payer Model (APM).† Value-based contracting under the APM authorizes CMS "to provide payment flexibility and local control in exchange for meeting quality, financial, and scale targets, as well as alignment across payers (including commercial payers)" for medical and pharmaceutical benefits. ⁸⁸ Under this agreement, providers and payers participate in both shared savings and shared losses. ⁸⁹ Vermont Medicaid found that removing PA for providers participating in the contract resulted in utilization increases. ⁹⁰ Vermont Medicaid's Chief Medical Officer suggested that these increases may be due to the program's limited downside risk, as well as the evolving development of providers' system controls. ^{11,90}

Prohibiting and limiting prior authorization. Increasing demands⁹¹ from providers and consumers to remove barriers to care have prompted individual states to reevaluate their PA practices, particularly within behavioral health services. For example, New York removed PA requirements in 2020 for the first 14 days of an inpatient admission for a mental health condition among children under age 18.^{92,93} The law applies to all commercial, Medicaid managed care, and Child Health Plus plans in the state. In 2022, a Massachusetts law was signed, that, among other provisions, requires payers to cover mental health acute treatments and stabilization services.⁹⁴ In addition, payers are required to eliminate PA for these types of services.⁹⁴ We could not locate published data on the impact of these new laws, however, anecdotal reports from

^{*} Currently, many provider organizations ask payers to retain administration of PA, due to either a lack of resources to implement their own UM methods or due to a lack of infrastructure to determine which services should be subject to PA.58

[†] Vermont's Medicaid, Medicare, and commercial payers participate in the APM.

Massachusetts suggest the changes have improved timeliness to care and reduced administrative obstacles to accessing mental health treatment.

At least 21 states and Washington D.C. have passed legislation that limits the use of PA for substance use disorder (SUD) services or medications. ⁹⁵ Of these, Delaware, Illinois, Maine, and Washington have limited PA for SUD services and medications among both commercial and Medicaid payers. ⁹⁵ For example, Delaware commercial and Medicaid payers may not subject diagnosis and treatment of drug and alcohol dependencies, including inpatient treatment, to PA. ⁹⁵

Establishing Trust in the Prior Authorization Process and Boosting Its Integrity

Transparency. Providers often express frustration with the PA process due to a lack of clarity surrounding whether a PA is required for select services or treatments⁵⁹—a pain point made even more apparent when PAs must be submitted manually. Fifteen states have acknowledged this and require payers to post items and services subject to PA, as well as medical policies, on their respective websites, especially in connection with prescription drug formularies.⁸²

With respect to improving insight into the efficacy of the PA process, 11 states require health plans and insurers to report PA statistics (e.g., number of approved PAs, number of denied PAs, number of PAs approved after appeal, etc.). Of the 11, only Arkansas, Minnesota, and Texas are required to make these statistics available to the public and post them on their respective websites.⁸²

Rewarding Provider and System Performance

Gold-carding. Performance-based reforms have seen sporadic uptake at the state level. According to the 2022 Prior Authorization State Law Chart, only five states have required either public or commercial payers to implement or pilot gold-carding programs, although recent momentum has grown. Vermont implemented a gold-carding program for radiology within its Medicaid program, and its Department of Health Access reported

^{*} Louisiana, Michigan, Texas, Vermont, and West Virginia

"a notable example of success in improving clinal results and reducing administrative burden for healthcare professionals." We were unable to locate this report to include more details.

The Texas gold carding legislation has, however, received extensive commentary. Passed in 2021, HB-3459 requires payers (not including the state Medicaid program or specific child health plans), to "gold-card" providers who meet or exceed a 90% PA approval rate for certain health services (effective January 1, 2022). 97 Under this program, plans identify eligible providers and provide them the opportunity to participate. Participating providers receive evaluations* from health plans every six months to ensure that their practice patterns for services normally subject to PA do not result in overutilization or medically inappropriate use because of their exception or "gold-card" status.

In March 2023, Becker's Hospital Review, a healthcare industry reporting outlet, published an article on perceptions around the gold-carding program in Texas, claiming that the program was not yet meeting the expectations of providers in the state. Providers reported that the program's guidelines were unclear. An update in May 2023 reported that few providers seem to be eligible for the program; questions about which services are covered by the program persist. 97

Several other states have attempted to legislate similar performance-based programs. Without the same success, Colorado, 99 Indiana, 100 Kentucky, 101 Mississippi, 102 New York, 103 and Oklahoma 104 also proposed gold-carding bills during the 2021-2022 Legislative Session. 105 It bears stating the obvious (in addition to challenges noted above regarding disparate impacts of gold carding programs): Since gold-carding programs may apply only to certain services and can vary substantially by payer, they introduce additional variability in the process, which may override the benefits of reductions in PA requirements.

^{*} Plans retrospectively review a random sample of 5-20 claims submitted by the provider during the most recent evaluation period.⁹⁷ At least 90% of the claims from the random sample must meet medical necessity criteria that would have been used by the payer for the particular service.⁹⁷

California Prior Authorization Efforts and Reforms

California has passed an assortment of laws affecting PA requirements. These laws impact prescription drugs and behavioral health services in particular and aim to improve the PA process, establish trust in its integrity, and reward providers based on their performance.

Improving the Prior Authorization Process

Standardization. In 2015, CA passed a bill (SB-282) requiring payers^{*, (106)} to create and accept a standardized form (Form 61-211), no more than two pages in length, for PA related to prescription drugs or step therapy exemptions.¹⁰⁷ The law included the following requirements:

- The form must be electronically available; 107
- Providers must use the standardized form or complete requests using a process that meets the NCPDP SCRIPT standard for ePA transactions;¹⁰⁷
- Payers must respond to urgent requests within 24 hours and non-urgent requests within 72 hours of receipt. ¹⁰⁶ If the provider does not receive a response within the specified timeframe, the request is considered approved. (Note: Medi-Cal Managed Care contracts are exempt from the timeframe requirements.) ¹⁰⁶

In addressing access to behavioral health, CA requires payers, including commercial and Medi-Cal managed care plans, to ensure that medical necessity criteria and other UM processes align with recent changes made to the California Mental Health Parity Act. This includes "requiring [payers] to cover medically necessary prevention, diagnosis, and treatment of all mental health conditions, as well as substance use disorders, that are listed in the most recent version of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) or the mental and behavioral disorders chapter of the most recent edition of the *World Health Organization's International Statistical Classification of Diseases and Related*

^{*} The standardized form and response timeframes do not apply under specific risk-arrangements, such as when "a contracted physician group is delegated the financial risk for prescription drugs by a health care service plan; a contracted physician group uses its own internal [PA] process rather than the health care service plan's [PA] process for plan enrollees; [and] a contracted physician group is delegated a [UM] function by the health care service plan concerning any prescription drug, regardless of the delegation of financial risk." There are additional exemptions spanning multiple chapters of Part 3 of Division 9 of CA's Welfare and Institutions Code.

Health Problems (ICD-10)." "[M]edical necessity determinations... must [also] be made using the most recent versions of clinical practice guidelines developed by nonprofit professional associations for the relevant clinical specialty." California's requirements are similar to those of other states. Illinois passed a similar bill in 2021, which requires Medicaid managed care plans and commercial insurers to utilize recognized medical necessity criteria for mental and behavioral health, as published by clinical societies. Oregon has also enacted similar legislation. There may be others who have standardized their medical necessity criteria in this area; our search here is ongoing. We could not identify examples of standardized medical necessity criteria in other service areas.

Automation. California is also promoting PA automation, which would further standardize the method by which they are submitted. In 2023, the CA Senate and Assembly passed SB-582, which requires commercial payers to establish and maintain specified application programming interfaces (APIs), including the FHIR PARDD API. The bill was contingent on CMS' finalization of its Proposed Rule.⁸⁴ It was vetoed by the Governor, who maintained it was premature and said the state should prioritize the California Health and Human Services Agency's (CHHS) Data Exchange Framework (DxF), which is currently undergoing implementation.⁸⁴ While the DxF aims to increase healthcare interoperability, it is not (yet) designed to allow for automated PA transactions. The bill was sent back to the Senate, where the Governor's veto is under consideration.⁸⁴

Prohibiting prior authorization. California prohibits commercial payers from using PA or other UM procedures for a select number of services, including behavioral health crisis stabilization services;¹¹⁰ contraceptive drugs, devices, and products;¹¹¹ and abortion services, which include follow-up services.¹¹² The latter two also apply to Medi-Cal Managed Care Plans.

Establishing Trust in the Prior Authorization Process and Boosting Its Integrity

Transparency. To increase transparency on prescription drug costs and UM provisions, CA requires certain payers to post and update on a monthly basis their prescription drug formularies. They must also use a standardized formulary template, on which they must include information such as cost-sharing tiers and utilization controls, including PA requirements. This requirement appears more limited than what is

mandated in other states (which we discuss above) because it does not require payers to list medical services subject to PA.

Rewarding Provider and System Performance

Gold-carding. The CA Legislature is considering. (115) a bill that would require payers to support a PA exemption process (i.e., gold-carding) for providers who, in the previous 12 months, demonstrated a ≥90% approval rate for most services and brand-name prescription drugs subject to PA. 116 In addition to establishing a gold-carding program, commercial payers and Medi-Cal managed care plans regulated by DMHC would be required to establish an ePA process, track their annual approvals, denials, and appeals, and remove PA from the products and services with a ≥95% approval rate. 116 It is important to note that PA removal would not apply to services provided through fully-integrated delivery systems or by physicians who have assumed responsibility for PA under a risk-bearing agreement. 116 (Payers and providers in these types of arrangements determine whether and when to apply PA and are exempt from reporting requirements.) We note that findings from the CHBRP survey indicated virtually no use of gold-carding for pharmaceutical drugs in CA.8 On the other hand, some respondents reported gold-carding efforts for certain medical services and found "mixed results."8 The report did not provide further details.

California professional societies have expressed mixed support for the gold-carding bill. The California Medical Association (CMA) includes the gold-carding bill among six other priority bills for 2023.¹¹⁷ The California Association of Health Plans (CAHP), however, does not support the bill. CAHP released a two-page flyer arguing the bill would increase medical waste, fraud, and abuse. It states that "SB 598 gives specified providers a blank check to perform and/or prescribe medically unnecessary procedures and medications."¹¹⁸

^{*} A recent update from the CMA states that language from the bill (SB-598) was included in an amended version of SB-516, which will allow the Legislature to continue to consider the bill when its session resumes on January 3, 2024.¹¹⁵

General Provisions*

California payers are required to respond to medical benefit PA requests in a timely fashion. The regulation states that payers must make PA decisions within five business days of receipt. In urgent cases, payers must make their decision within 72 hours. Once a decision is made, the payer has 24 hours to communicate the decision to the provider.

Finally, CA has passed other PA statutes to address prompt access to care. For example, in 2021, CA codified requirements that require payers to offer urgent care appointments to enrollees for services not subject to PA within 48 hours (two days), and non-urgent care appointments for services subject to PA within 96 hours (four days). 120, 121

Voluntary Prior Authorization Efforts and Reforms

Voluntary reforms by national insurers and organizations are mainly focused on improving the PA process by automating transactions, implementing artificial intelligence (AI), and removing PA across all providers in select services and in other cases, based on providers' and systems' performance. Several efforts are in early stages and we could not locate data on outcomes.

Improving the Prior Authorization Process

Automation. Many payers are focused on streamlining the PA process using automation. For example, Blue Shield of California participated in AHIP's Fast Prior Authorization Technology Highway (Fast PATH) in 2020 with five other health plans across the U.S.¹²² An evaluation of the 12-month project compared PA transaction data before and after ePA implementation and reported 71% of "providers who implemented ePA reported faster time to patient care." In addition, over 50% of providers reported fewer phone calls and 60% reported that ePA made it easier to understand if PA was required. 122

^{*} It remains unclear the extent to which PA is applied in risk-based contracts in CA. We note this in an earlier section when we describe findings from the CHBRP's October 2023 report on PA in CA.

Others have only just announced their intent to automate. CVS Aetna revealed in March 2023 that it was focusing on automating the PA process, though we could not find information on its progress.¹²³

Artificial Intelligence. Al is similar to automation (which we describe above) in its use to minimize or avoid human intervention, but they are not synonymous. Use of Al in PA "leverages computers and machines to mimic the problem-solving and decision-making capabilities of the human mind." ¹²⁴ As recent suits have shown, Al is controversial. The alleged use of Al for PA and claim denials has led to lawsuits against Cigna and UnitedHealthcare (UHC), two major insurance companies. ¹²⁵

Nevertheless, Al's growing force in healthcare has the potential to ease PA administrative burden. Several articles^{126, 127, 128} outline ways in which AI can advance automation by helping to "organize information from EHRs, emails, policies, medical protocols, and other sources, vastly reducing low-value, time-consuming tasks involving searching, collating, and cross-checking information" that normally occur manually.¹²⁸

Health Care Service Corporation, whose subsidiaries include several Blue Cross Blue Shield payers, piloted an AI tool in 2022 across behavioral health and specialty pharmacy services "that streamlines the submission process and provides autoapprovals when clinical criteria are met" and either approves the PA or sends it to a human for review;¹²⁹ the tool does not deny requests.¹³⁰ Participating organizations saw approval rates of 80% and 66% in behavioral health and specialty pharmacy, respectively.¹³⁰ As of 2023, the pilot has expanded to include additional service areas, such as inpatient acute care, skilled nursing care, and home health.¹³⁰

Other companies have announced their upcoming AI-enabled products. ^{131, 132} For example, Blue Shield of CA announced a partnership with Google Cloud in 2023 to "pilot [AI] and machine learning technologies to help expedite the [PA] process and get medical decisions back in the hands of providers faster, and enable a real-time exchange of data. ^{131, 133} No data or other information on pilot results were available at the time of this report.

As with automation, barriers remain to implementing AI. First, there is concern surrounding how AI will be regulated in healthcare. The Biden Administration acknowledged this, issuing an executive order in late October 2023, that calls on HHS

"to establish an AI Task Force[†] within 90 days that will, within a year, develop policies and frameworks on responsible deployment and use of AI and AI-enabled technologies in the health and human services sector." Some states, including CA, are also moving quickly and have introduced similar legislation. Second, providers and payers must have reliable and proper technology to support AI; they must be able to determine what information to extract and how to use it to avoid bias in decision-making.

Proactive Authorization. Proactive authorization, or pre-authorization, is a patient-specific process that preapproves patients for downstream services related to their primary diagnoses.⁵⁸ This form of proactive authorization works well with established and relatively fixed courses of treatment.

Cohere Health, an automated technology service provider, developed a PA solution that incorporates the American Academy of Orthopaedic Surgeons' (AAOS) Clinical Practice Guidelines for musculoskeletal (MSK) care into its automated care paths and utilizes AI and machine learning to allow providers to request PAs for an entire episode of MSK care, rather than for one service at a time. Humana partnered with Cohere to pilot the automated PA solution in 12 states and was able to use it to process 95% of MSK PAs with a median approval time of zero (0) minutes. Additional findings showed high rates of satisfaction from participating providers. In early 2022, Humana announced that it would expand use of the PA automation platform for MSK procedures to additional service areas and across all U.S. states for its commercial and Medicare consumers, following the successful pilot.

Humana announced in late 2022 that it would continue the partnership and begin using Cohere's digital UM collaboration platform for cardiovascular and surgical services across its Medicare Advantage members and Humana employees with the company's health plan. Thus far, it appears Humana has designated a list of cardiovascular, surgical, and endoscopy procedure codes for which a PA must be submitted through Cohere's platform. We reached out to our contact at Cohere Health for preliminary findings from the program's expansion.

^{*} The Task Force will also develop guidance on monitoring the technology, including ensuring equity and avoiding bias.

[†] The law would provide requirements and standards surrounding the development, implementation, and further scaling of AI models across the CA market. 135

Removing prior authorization requirements. Major insurers, such as UHC, are responding to calls to remove PA. Earlier this year, UHC announced that it would remove* (141) PA requirements from 20% of its items and services currently subject to PA. 142 Prior authorization requirements were removed from certain CPT codes within several service areas across different plans; for example, UHC removed PAs from certain CPT codes in service areas under their commercial plans, such as DME, genetic testing, and site of service. 143 Under its Medicare Advantage Plans, UHC did not remove PA for certain sites of service codes but did remove PA for certain orthopedic/prosthetic codes. 144 UHC has not published its rationale for doing so.

Other major insurers (e.g., Cigna Healthcare and two Blue Cross Blue Shield plans) announced similar streamlining efforts. Cigna removed approximately 600 PA requirements, which constituted approximately 25% of its total PA requirements, citing provider and clinician demands to remove burden from the PA process. The payer announced that it would remove an additional 500 PA requirements from its Medicare Advantage plans later in 2023. Blue Cross Blue Shield of Michigan announced that it will eliminate 20% of PA requirements across its commercial and Medicare plans, for certain procedures such as bariatric surgery, breast biopsy, and cardiac rehab services. Blue Cross Blue Shield of Massachusetts shared in November 2023 that it would remove PA requirements across commercial plans for home care services including physical therapy, occupational therapy, home health aide and nurse visits, and social worker visits. Cigna PA

These moves accede to calls for reform but nevertheless affirm payers' desire to maintain control of the PA process.

Rewarding Provider and System Performance

Gold-carding. UHC's plan to implement a national gold-carding program in 2024 for provider groups is also intended to reduce the number of PAs required. The health insurer claims that the program will eliminate PA requirements for most procedures

^{*} The PA cut went into effect on September 1, 2023 for UHC commercial plans, individual exchange plans, and Medicare Advantage plans, and will go into effect for its community plans, which include Medicaid and dual eligible special needs (D-SNP) plans, on November 1, 2023. 141,142

None of the major insurers provide their rationale for removing PAs in certain categories across specific markets.

if provider groups meet the eligibility requirements.¹⁴⁹ We could not determine the program's requirements at this time.

Blue Cross Blue Shield of Michigan also announced it would expand its current gold-carding program. The health plan will exempt physicians who have a proven record of evidence-based decisions from the PA approval processes in certain circumstances. Blue Cross Blue Shield of Michigan's current gold-carding program exists in partnership with the Michigan Radiation Oncology Quality Consortium for radiation oncology procedures and began in 2017. There is not yet information on the types of physicians or services that will be eligible once the program expands.

Other payers have voluntarily implemented gold-carding programs with different degrees of success. Results from AHIP's survey on PA and payers' application of gold-carding among commercial payers reports that while 46% of respondents reported their respective gold-carding programs' reduced administrative burden and improved provider satisfaction, 33% claimed that the programs were administratively difficult to implement, 20% reported "performance slippage," and 20% noted higher costs without improved quality.¹⁰

Centers of Excellence. A select group of payers and large employers^{† (151, 152)} have developed contracts through which they waive PA, generally for circumscribed complex services, when those services are provided at a designated "Center of Excellence" (COE).^{‡ (153, 154)} Walmart, for example, provides insurance benefits that do not require PA for cardiac surgery provided at Cleveland Clinic. It also waives PA for joint replacement surgery performed at Johns Hopkins Hospital and for transplants. Similarly, UHC, acting as a third-party administrator, waives PA for bariatric surgery, among other services, if the service is performed at a designated COE.¹⁵⁵

Centers of Excellence serve to concentrate care in a limited number of locations. While some argue that this decreases competition, the counter has validity: services rendered

^{*} The most common gold-carded service areas included high-tech imaging (44%), orthopedic services (19%), elective inpatient medical services (19%), and cardiology (19%).¹⁰

[†] Several corporations^{151,152} plan to or currently contract with COEs, including Lowe's, McKesson, JetBlue, Boeing, and Walmart.

[‡] Payers customize criteria and evidence to determine which hospital systems or provider groups qualify as a COE or "high value" provider within a geographic area. 153,154 Generally, quality and utilization measures are considered.

at COEs produce high-quality health outcomes* for complex services provided at a greater volume. ^{153, 154} The impact on PA reductions, however, is not clear. We are unable to determine what percentage of PA processes are waived in conjunction with the existence of designated COEs.

Additional Reform Efforts

In this section we describe and comment on UM practices seemingly adjacent to the prior authorization process but ones that could be applied instead of prior authorization.

Rewarding Provider and System Performance

Global Appropriateness Measures. Global appropriateness measures (GAM) are a new, provider-driven solution to identify low-value care and reduce clinical waste. Using stakeholder and expert input as well as current medical literature, GAM has developed measures of appropriateness, or metric algorithms, in clinical areas that appear to have variation and overuse. Payers and providers can define utilization thresholds and apply these to their own datasets for specific services within specialties (e.g., as of 2021, there are 12 measures related to Mohs surgery).

Health plans and providers may join the GAM consortium, through which they would receive access to a full library of measures. They may also select to target certain specialties, without utilizing the full set of measures. GAM's analyses also assist health plans in determining areas to target based on their networks' utilization patterns and potential economic benefits. GAM provides various levels of support, including data analysis, threshold definition, and guidance to reduce inappropriate utilization. For example, GAM may prepare "Dear Doctor" letters that present unique service utilization data. The letters also identify the threshold within which providers should aim and show the recipient where they fall along the distribution. GAM asserts that clients have reduced variation in this way and that the "Dear Doctor" letters have led to long-term behavior change. 157, 158

^{*} Optum reports that its COE patients are more likely to receive more accurate diagnoses, higher survival rates, coordinated, patient-centered healthcare, appropriate therapy, fewer complications, shorter length of inpatient stays, and decreased out-of-pocket costs, compared with non-COE facilities.¹⁵⁴

To our knowledge, GAM has not specifically targeted services subject to PA, though a possible reform effort could include creating and implementing measures of appropriateness for services subject to PA. Providers and payers could agree on select services subject to PA that have high rates of approval and/or services subject to wide variation in utilization. Payers could then apply GAM's methodology to avoid imposing PA for select services they are currently evaluating and avoid an additional layer of administrative burden. This effort could also be seen as an alternative to gold-carding.

Considering Utilization Management Practices Adjacent to the Prior Authorization Process

Clinical Utilization Review Boards. The Vermont Legislature required the Department of Vermont Health Access (DVHA)¹⁵⁹ to appoint a Clinical Utilization Review Board (CURB), comprising 10 clinicians appointed by the Governor, and is assigned with reviewing and identifying appropriate medical utilization as it relates to medical necessity, cost-effectiveness, and feasibility.

The CURB makes recommendations to DVHA regarding coverage, unit limitations, place of service, and appropriate medical necessity of services in the State's Medicaid program. The CURB was directed to consider "the possible administrative burdens or benefits of potential recommendations on providers, including examining the feasibility of exempting from PA requirements those health care professionals whose [PA] requests are routinely granted." Board members, including practitioners with diverse experiences, make recommendations to the DVHA Commissioner to implement alternative solutions to UM and/or waive PA, based on clinical data for specific services subject to PA, such as those readily approved, at low cost, or those posing zero risk to patients. Meetings and meeting minutes are public.

To our knowledge, CURBs have not been implemented in other states, however, Drug Utilization Review Boards (DURBs)* (160, 161, 162) may provide a basic framework for which the formation and implementation of a CURB may be considered in other states.

Conclusion

Prior authorization differs in its purpose and application across various types of health plans, policies, and risk arrangements, especially in CA. We found little information that allows us to quantify the way in which PA is applied across the state, making it difficult to size the issues faced by all stakeholders involved (i.e., payers, providers, and consumers).

Because concerns related to PA persist, despite acknowledged benefits, reforming the PA process has increasingly become a multi-stakeholder call to action over the last decade, although providers are more commonly the drivers of reform proposals. Overall, efforts to remove cost and burden have focused on standardizing the process, implementing technological solutions, and reducing PA requirements. Because providers and consumer/patient advocates continue to voice a lack of trust in the efficiency and efficacy of the PA process, proposals to increase the transparency of decision criteria and PA outcomes have become widespread.

It is difficult to recommend potential reform efforts that could prove meaningful in CA at this stage without a better understanding of their potential impact, in terms of the issues they will ameliorate, the scope of their reach, and the additional burdens they may create. California stakeholder input—and additional data—are needed.

NEHI's next steps include disseminating a survey on PA to understand CA stakeholders' views on the application of PA, the use of PA and its impact, the effectiveness of PA, and

^{*} Under the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), state Medicaid programs were required to establish DURBs. ¹⁶⁰ DURBs function proactively and retroactively to identify drugs and drug classes that are inappropriately prescribed or present safety issues. ¹⁶⁰ Once such issues are identified, the DURB can consult with providers, pharmacists, and other experts to determine whether UM functions, such as PA, should be applied and what medical necessity criteria must be met for approval. DURBs are also required to annually report on cost avoidance/cost-savings, among other metrics. Data from 2021 showed cost-savings across 49 states (ranging from approximately \$5,775 [lowa] to \$777.4 million [Colorado]), ¹⁶¹ however, cost-savings calculation methodologies vary by state, preventing program data comparisons across states. ¹⁶²

the major reform efforts that could prove useful and scalable across the state. NEHI will supplement survey findings with interviews and begin to craft recommendations on ways to pursue state-wide PA reform efforts, given both common and disparate stakeholder priorities.

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