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<u>NEHI</u> is a nonprofit, unbiased organization with members, including providers, hospitals and health systems, payers, pharmaceutical and biotech companies, and medical device and technology providers, as well as associations and consultants. Through interdisciplinary collaboration and with its members' guidance, NEHI researches and examines tough and timely health care innovation issues from multiple, often divergent perspectives. It then address policy and adoption challenges to promote the value of innovative products and processes.

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About the Foundation

The <u>California Health Care Foundation</u> is an independent, nonprofit philanthropy that works to improve the health care system so that all Californians have the care they need. We focus especially on making sure the system works for Californians with low incomes and for communities who have traditionally faced the greatest barriers to care. We partner with leaders across the health care safety net to ensure they have the data and resources to make care more just and to drive improvement in a complex system.

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Executive Summary

Prior authorization (PA) is a utilization management (UM) tool used by health plans and risk-bearing medical groups to discourage inappropriate, lowvalue, or unsafe care and ensure that patients receive services that are covered by their benefit plan and delivered by a contracted provider.

Despite the important role that PA plays in the health care system, there is widespread consensus that the processes by which it is carried out warrant significant improvement. Based on extensive input from industry leaders and consumer advocates, the five highest-priority issues around PA process improvement in California are the following:

- 1. The lack of information on PA requirements at the point of care adds to the cost of PA for providers and payers. The absence of critical information on PA requirements, medical necessity criteria, and documentation requirements at the point of care drives costs and increases burden among providers and payers, who may then have repeated exchanges before a decision is made, thereby delaying patient care.
- 2. Data about the PA process and its impact are not shared publicly or at actionable levels. Although there are many calls to reform the PA process, there is little publicly reported information on the process or its outcomes, making it difficult to pinpoint the issues (beyond anecdotal evidence). This engenders mistrust among providers and frustrates payers, who consider certain PA data to be proprietary.
- 3. Repeat PAs and concurrent reviews during a course of treatment interrupt patient care and may expose patients to financial liability. Multiple evaluations of a care plan add burden to all parties, especially patients, who may experience care interruptions or delays and face

financial liability for care deemed unnecessary when there has been no change in their condition or the evidence base for their prescribed course of treatment.

- 4. PA requirements are not well understood by patients or providers, resulting in the perception that there are "too many" PAs. The reasons for a PA requirement are not transparent in many cases. This raises questions about unnecessary variation in PA requirements, generates mistrust, and contributes to the perception that the growth in PA is unjustified.
- 5. There is a perception among providers and patients that medical necessity determinations for certain types of complex care are made by health care professionals without the requisite expertise. Requests for highly specialized or complex treatments, as well as for certain types of behavioral health care, are seen as exceeding the expertise that reviewers have. This may further delay treatment as providers must spend more time in peer-to-peer conversations or appealing denials.

After reviewing current California laws and regulations, federal and state policy developments, and recent proposals advanced by patient advocates, industry stakeholders, and academic experts, the authors determined that the following four potential approaches share closest alignment with the above priorities:

 Mandate technical requirements to advance adoption of automation. Recently finalized federal regulations (i.e., the final rule) put their weight behind the benefits of automating PA to address waste in the process. Through adoption of new application programming interface (API) requirements and Fast Healthcare Interoperability Resource (FHIR) standards, the final rule will automate determinations of a patient's health plan coverage, confirm or rule out the need for PA, identify documentation required for approval, and facilitate the exchange of information with minimal administrative involvement, thus addressing many of the most vociferous objections to the PA process. The final rule applies to many public payers but does not apply to fully insured commercial products or self-insured plans. States can accelerate adoption by mandating automation or otherwise providing strong incentives to automate PA processes for all payers subject to state regulation, thus tipping the scales among payers to advance a reform that will have a significant impact.

California could also consider requiring providers and payers impacted by the state's data sharing agreement to support PA FHIR APIs as defined by the HL7 (Health Level Seven International) Da Vinci Project standards (i.e., those outlined and recommended within the final rule). The agreement currently promotes data exchange between health care entities and governmental agencies to provide a complete picture of a patient's health history. FHIR-based exchanges are not currently required. Mandating their use among providers and payers would complement the push to enable automated PA transactions and bolster real-time data exchange.

2. Refine public reporting requirements to promote trust and enable dialogue about additional reforms. Public reporting of data related to the PA process in California is limited, and stakeholders have noted that the information provided is general, making it difficult to draw actionable conclusions. The recently finalized CMS (Centers for Medicare & Medicaid Services) rule on PA — which requires certain payers to collect and publicly report all items and services that require PA, the percentage of PAs approved after appeal, and other metrics — recognizes that access to information is essential to understanding issues

with PA and assessing the potential impact reforms may have on the PA process. By building on federal requirements and extending their scope to include state-regulated commercial payers as well as provider organizations that have assumed responsibility for PA, California can enable a broader analysis of the issues, as well as create a transparent basis for trust and reforms. Engaging a multi-stakeholder task force to inform the requirements may help ensure that the data requested are at the right level of specificity to explain and improve the PA process.

3. Extend the duration and scope of PA approval for ongoing care with a defined and accepted course of treatment. Several states have addressed the frequency with which PAs are required by extending the duration of time for which an approval is valid. Likewise, they have addressed the issue of concurrent review in this manner. Policies vary widely; some simply extend the duration of a PA approval for a set period, while others prescribe the duration of an approval for certain types of care under certain conditions.

Developing an approach focused on avoiding repeat PAs for chronic care or care that is subject to well-defined protocols should be a priority. And even in these circumstances, care may require review to ensure it remains effective. In addition, California could consider straightforward and broader protection for patients who change plans during a treatment course. While current California law contains continuity-of-care requirements for enrollees under certain circumstances, the requirements do not address the application of PA to an ongoing treatment course. A growing number of states have adopted prohibitions against an enrollee's new plan denying care through PA for a defined period.

4. Develop transparent principles for the annual review of PA requirements. California requires payers to annually update their criteria or guidelines used in making PA decisions to ensure that they remain current with evidence used to determine medical necessity. Adopting a related policy that requires payers to annually review their PA requirements and publish the principles on which their reviews are based may be warranted. According to multiple surveys, most payers currently evaluate whether to maintain or remove services subject to PA. The articulation of principles for those reviews maintains payers' autonomy and discretion but also provides regulators and other stakeholders with a benchmark against which to assess the integrity of the review process. Further, it allows providers and patients to better understand the reasoning behind specific PA requirements and changes, hopefully enhancing trust in the review process.

These recommendations are feasible first steps in an ongoing review of PA, which should be made possible by enabling greater access to meaningful data about the process and its impacts. By prioritizing issues that require attention from the vantage of multiple stakeholders in the UM process, the authors believe it is far more likely that collaborative solutions can be devised to enhance respect for and confidence in the PA process.

Context

Prior authorization (PA) is a utilization management (UM) tool used by health plans and risk-bearing medical groups to discourage inappropriate, lowvalue, or unsafe care and ensure that patients receive services that are covered by their benefit plan and delivered by a contracted provider.

Despite the important role that PA plays in the health care system, there is widespread consensus that the processes by which it is carried out warrant significant improvement. The American Medical Association (AMA) reported in 2023 that at least 30 states had proposed efforts to improve the process by requiring reviewers to issue PA decisions within a shortened time frame, extend the amount of time for which a PA approval remains valid, publish data on the process and its outcomes, and limit or eliminate PA requirements by physician or service.¹

California has considered and enacted multiple PA reforms over the years. In 2021, the state began requiring payers to cover medically necessary mental and behavioral health services and issue medical necessity determinations "using the most recent versions of clinical practice guidelines developed by nonprofit professional associations for the relevant clinical specialty."² Policymakers are currently considering a "gold-carding" bill that would, among other provisions, exempt eligible physicians from PA requirements.

This paper contributes to PA reform considerations and discussions in California by summarizing the literature on federal, state, and industry PA reform efforts; reporting the results of a multi-stakeholder assessment on the benefits and burdens associated with the current process in California; and prioritizing a set of issues and recommendations for reform.

Findings

Prior Authorization Benefits

The literature search and stakeholder feedback (via surveys, interviews, and regular Advisory Committee meetings) all revealed significant benefits to retaining the use of PA in California's health care system. (See Appendices A and B for further information on study methods and participants as well as interview questions, respectively.)

Prior authorization ensures that care is medically necessary and safe.

The majority of providers and payers who provided feedback throughout this project agreed that PA drives both the use of evidence-based care and flags care that could be potentially harmful. They found the process necessary, as it provides an opportunity to review a treatment plan before it is offered to a patient and, if needed, direct the ordering provider to a more appropriate pathway. The authors' interim report published in November 2023 provided several examples of these benefits.³ For instance, a Centers for Disease Control and Prevention (CDC) report by Faul, Bohm, and Alexander found an association between Medicaid preferred drug lists that require PA for methadone and lower rates of methadone overdose among enrollees.4

Relatedly, PA is used to reduce unnecessary costs by avoiding potential misuse (see sidebar) and directing providers and patients toward lower-cost treatment options.⁵ A systematic review found evidence that the use of PA in Medicaid and Medicare programs increased generic prescription drug use, which "reduced patient and payer's spending on prescriptions without causing deterioration in patient's health-related quality of life."⁶ A study by the American Enterprise Institute (AEI) examined the effect of applying PA on prescription drugs covered under Medicare Part D and the program's net costs.⁷ The AEI found that by using PA and directing beneficiaries to lower-cost options, the Medicare Part D program reduced the use of drugs subject to PA by 25% and overall Part D spending by 3% — an estimated reduction equivalent to \$95.88 per beneficiary-year.⁸ The authors of this study also found that the administrative costs to run PA are merely 6%–18% of the size of the spending reduction that can be achieved through the UM process.⁹

The Center for Medicare and Medicaid Innovation (CMMI) reported that requiring prior authorization for nonemergency ambulance transportation among Medicare beneficiaries lowered unnecessary use by more than 70%, which in turn lowered total Medicare spending by nearly 2.5%, without affecting beneficiaries' quality of or access to care.¹⁰

Prior authorization confirms that care is covered and delivered in the right setting.

Provider and payer stakeholders were also united in the notion that PA ensures that the care requested is a covered benefit under the patient's plan and delivered in a cost-effective setting. Patients participating in health maintenance organization (HMO) and some point of service (POS) plans are restricted to services from certain providers; there are financial liabilities associated with "out of network" care. In this context, PA functions to ensure care is provided in network; it may also provide the authorization necessary to avoid financial liability by approving an out-of-network provider.

PA also functions to direct care to less expensive settings (e.g., from inpatient to outpatient facilities, or from academic medical centers to community hospitals). Providers in capitated arrangements (receiving per-member per-month [PMPM] payments) are particularly sensitive to ensuring that care is delivered at the appropriate and least expensive location.¹¹

Prior Authorization Issues

Although PA as a concept gives rise to several benefits, stakeholders identified five priority issues around improvements to the process for California policymakers to consider. (See Appendix C for a brief description of additional issues beyond these top five.)

The lack of information on PA requirements at the point of care adds to the cost of PA for providers and payers.

There was agreement across all stakeholders that the current PA process does not facilitate quick or efficient access to information on PA requirements, contributing to increased burden and costs for both providers and payers. All providers expressed frustration in their inability to confirm whether PA is required. Lack of clarity on this seemingly simple point often prompts providers to submit "unnecessary" PA requests to ensure that they or their patients are not financially responsible for the care delivered. This process requires time and resources — for providers to submit requests and for payers to process and respond to them.

Providers also described difficulty in accessing medical necessity criteria associated with a specific request prior to and during the submission process. Although California law requires payers to make the criteria available to whoever requests them, via either mail or electronic means,¹² providers stated that they require the information at the point of care. It is generally unavailable there or cumbersome to access in their workflow. Providers also noted that it was often unclear what documentation they must submit to demonstrate compliance with medical necessity criteria. Although it was not possible to quantify the issue, a dominant complaint from providers was the time and effort necessary to respond to requests for additional information and to appeal denials due to inadequate documentation.¹³ The literature scan also highlighted this issue, noting its contribution to physician burden

and added costs.¹⁴ Hospitals' administrative costs to overturn claim denials were reported to be nearly \$1, \$48, and \$64 per claim across Original Medicare, Medicare Advantage, and commercial payers, respectively, based on a recent survey on hospital claims data.¹⁵ (The same study found that almost 15% of all claims in 2022 were denied and that 3.2% of all denied claims were preapproved through the PA process.¹⁶) Less is written about the costs incurred by payers relating to multiple reviews of a PA request, but these certainly exist.¹⁷

Multiple exchanges between payers and providers in connection with a PA request lead to delays in authorization decisions, and, consequently, can contribute to health disparities by delaying patients' care or prompting patients to either abandon care or assume the costs of care, if they are able.¹⁸ California law contains stringent time frames around PA decisions in an attempt to combat delays; for urgent and nonurgent medical benefit requests, decisions must be made within 72 hours and five business days, respectively.¹⁹ The decision must then be delivered to the provider within 24 hours.²⁰ In cases when care is denied or modified, the decision must be communicated in writing to the patient within two business days.²¹ For prescription drug authorizations, urgent and nonurgent decisions or requests for additional information must be made and delivered within 24 hours and 72 hours, respectively, or the request is deemed approved.²² Nevertheless, and perhaps because requests for additional information can delay decisions even with these time limits in place, there remained a shared perception among providers and consumer advocates that it takes too long to receive a PA decision.

Data about the PA process and its impact are not shared publicly or at actionable levels.

The Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) are regulatory agencies charged with overseeing the

provision of health insurance in California, including Medi-Cal managed care plans and state-regulated commercial payers. Both agencies collect and audit payer data on the PA process. Most of these data are not, however, made public.²³ The DMHC's 2022 annual report, which covers the agency's annual activities, reports generally on plans' PA processing violations and the associated corrective actions (i.e., fines) as well as results from its Independent Medical Review (IMR) program, which handles patient appeals following a PA denial.²⁴ Data providing information at an organizational level (e.g., on PA denials by payer, service, and reason) are not disclosed.

A report by the California Health Benefits Review Program (CHBRP) on the state of PA in California highlighted limitations in its findings due to gaps in available PA data. The California legislature directed the organization to provide an overview of PA within the state, including the number and types of tests, services, and treatments 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.²⁵ CHBRP conceded its findings were "limited as to the extent to which ... state-regulated health insurance in California ... uses [PA] and its impact on the performance of the health care system, patient access to appropriate care, and the health and financial interests of the general public," as the information it was able to provide was from a one-time survey CHBRP itself administered.²⁶ State regulators interviewed for this project implied that their vision was likewise incomplete: the data they provide publicly constrains evaluation of PA processes and issues in California and hampers comparison of PA functions in California with those in other states.

Aggregated rates of PA outcomes (such as those listed in CHBRP's report) do not provide a comprehensive picture of the PA process. In particular, denials and reversals on appeal do not reveal the extent to which denials are inappropriate — a concern noted by provider and consumer advocate participants in this project. Denials based on a lack of information might be appropriate and reversed once the information was supplied. It is essential to categorize reasons for denials, along with the services to which denials apply, in order to determine how to decrease them.

The absence of detailed data on PA outcomes is in line with criticisms about the transparency of the process. This exacerbates mistrust among providers and patients and prevents understanding and verifying PA issues — such as how PA affects patient outcomes — at a level of granularity that is actionable. In addition, the ensuing calls by stakeholder groups to remove PA requirements in their entirety undoubtedly irk payers, who must constantly remind them of the benefits of retaining the process.

Payer participants in this project, however, acknowledged complaints around the lack of information concerning the PA process and its outcomes. They noted that they may be willing to share additional data but were unwilling to share "proprietary" information. Further discussion is needed to identify their perspective on what data could be reasonably disclosed and analyzed.

Repeat PAs and concurrent reviews during a course of treatment interrupt patient care and may expose patients to financial liability.

Concurrent review, a form of PA, is applied during authorized episodes of care to ensure that individuals engaged in ongoing inpatient or outpatient care receive medically necessary care as well as "the right level of care at the right time."²⁷ This type of UM allows the reviewer to modify a planned course of treatment or deny further treatment if they determine the approved course raises quality-of-care or patient safety concerns.²⁸ Concurrent review thus serves a critical purpose, ensuring that the course of treatment initiated continues to be appropriate.

Alternatively, when concurrent reviews are used to validate a well-established protocol (such as for chronic care), the process generally causes unnecessary disruptions. Repeat PAs for chronic conditions or other defined treatment courses entail similar risks. Providers and consumer advocates expressed frustration that although they may perceive a care plan to be comprehensive and medically necessary, reviewers often retain PA as a "checkpoint" to reevaluate the current treatment or next step in the care plan, which can result in treatment modifications, delays, or denials, causing distress among patients. Even if multiple authorizations do not result in a denial, the provider, patient, and payer must repeatedly engage in the process, which places burden on all parties involved. In addition, consumer advocates and most state regulators noted that when plans deny coverage for treatment already provided, there is a risk that the patient and/or facility becomes financially responsible for the treatment.

California law includes continuity-of-care requirements to minimize care disruptions. These provisions are, however, only applicable under certain circumstances and do not explicitly prohibit plans from applying PA or other UM methods. Specifically, when an enrollee is seeing a provider whose contract is terminated, the "nonparticipating" provider must accept the enrollee's plan's contractual terms and the compensation "rates and methods of payment similar to those used by the plan or the provider group for currently contracting providers providing similar services who are not capitated."29 Furthermore, enrollees only qualify if they were receiving services for specific conditions (e.g., an acute condition, a serious chronic condition, pregnancy, etc.) at the time of their provider's termination.³⁰

California has a somewhat similar provision requiring plans to cover a prescription drug for an enrollee if it was previously covered by the plan, it was used to treat the enrollee's condition, and the prescribing provider continues to prescribe it for the enrollee.³¹ This law also does not seem to prevent plans from applying UM requirements.

PA requirements are not well understood by patients and providers, resulting in the perception that there are "too many" PAs.

California requires payers to annually review their medical necessity criteria for services subject to PA to ensure that the criteria by which they evaluate requests reflect the most up-to-date, evidence-based guidelines; however, the state does not mandate the frequency with which payers must review and update their list of PA requirements. Some providers and consumer advocates expressed concerns that payers continue to require PA for services that are at low risk for abuse (with well-accepted, evidence-based care standards) and are low-cost. There is not, however, consensus on this point. PA application has demonstrated benefits in the review of lower-cost therapies and generic prescriptions, which the authors describe in a previous section.³²

There remained a strong view that both payers and providers required discretion in the imposition of PA requirements. Moreover, most payers in California attest that they regularly review the services and drugs for which they require PA. Surveys by CHBRP and AHIP (formerly America's Health Insurance Plans) found that 100% and 96% of surveyed plans evaluate and update their PA protocols on an annual basis, respectively.³³ That said, there was also consensus that an annual review of the application of PA could be improved. In discussions for this project, mistrust in this process was apparent and included reference to decisions by several major insurers to remove PA requirements on the one hand while still adding additional requirements on the other. The criteria used in these decisions are not uniform or transparent. This inhibits the ability to evaluate the extent to which PA is applied and, therefore, whether the application of PAs serves both payers and other health system stakeholders.

There is a perception among providers and patients that medical necessity determinations for certain types of complex care are made by health care professionals without the requisite expertise.

California law states that "No individual, other than a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, may deny or modify requests for authorization of health care services for an enrollee for reasons of medical necessity."³⁴ It also requires health plans to sponsor formal education programs in certain service areas to educate reviewers on the most current criteria used to base authorization decisions.³⁵

Multiple providers and consumer advocates reported that requests for complex treatments or highly specialized care, such as more costly types of mental health and substance use disorder (SUD) care, are not reviewed by health care professionals with the appropriate expertise.³⁶ There is a perception among payers that this is a workforce issue, with certain highly specialized physicians in short supply; however, the evidence for this remains anecdotal. One participant also noted that information regarding plans' offerings of formal education programs is limited and not publicly shared. Without specialization-matched and informed peer-to-peer reviews, there is more room for delays in patient care and the distress associated with altering a planned course of treatment. In addition, burden and costs are added to the provider and payer sides of the transaction if appeals result from initial decisions.

Providers also noted frustrations in connection with step therapy requirements and reviewers' expertise. (Step therapy, a form of PA, requires patients to "undergo several classes of ... therapies [before] approval for a higher-cost or more experimental treatment."³⁷) They described experiences in which reviewers who did not have the appropriate training to review the type of request at hand have required patients to engage in a treatment course until failure — thereby delaying what providers attest is medically necessary care — before they authorized the treatment initially requested. Providers argued that some step-therapy requirements can irreversibly deteriorate a patient's condition.

Potential Approaches

Based on the issues described above, the authors, in consultation with industry stakeholders, prioritized several potential approaches to improve PA processes.

Mandate Technical Requirements to Advance Adoption of Automation.

Policymakers may wish to extend the application of the new rule on health care interoperability and PA to all regulated insurers in California, with incentives for providers to enable automated processing of PA requests. California policymakers may also consider updating technical requirements for impacted providers and payers under the state's data sharing agreement.

Mandate state-regulated payers to adopt federal automation requirements.

The Centers for Medicare & Medicaid Services (CMS) announced in January that they finalized a highly anticipated rule on health care interoperability and PA, signifying a major reform to streamline the PA process at scale. The final rule requires most public payers — excluding Medicare fee-for-service as well as commercial payers — to build and maintain a PA application programming interface (API) using Fast Healthcare Interoperability Resource (FHIR) standards by January 1, 2027, which will

allow provider and payer systems to automate the PA process from end to end.³⁸

The automated process is summarized in brief (see sidebar), though an extended description is available in a previous NEHI report.³⁹

Automated Prior Authorization Process

- A provider/their staff launches an inquiry through the electronic medical record (EMR) to see whether prior authorization (PA) is required for a particular service or treatment for a specific patient. Based on the reviewer organization's rules and the patient's plan benefits, the EMR will display a "card" indicating whether PA is required.
- In the event PA is necessary, the provider's system accesses and pulls the payer's medical necessity criteria — typically in the form of a questionnaire — and any additional documentation requirements.
- The reviewer's organization accesses the EMR to auto-populate the medical necessity questionnaire and identify the necessary documentation.
- The system flags for the provider/their staff areas in which information could not be autopopulated. The provider/their staff enters the remaining information. If all information is automatically gathered, the provider/their staff can review the request prior to submission or allow the system to automatically submit a completed request "bundle."
- The completed request bundle is electronically delivered to the reviewer organization, which often results in a real-time decision for less complex types of care. This decision, whether it is made in real time or later, is returned to the EMR.
- In some cases, the reviewer requires more information to issue a determination. In this case, the provider/their staff are asked for additional information through the EMR and prompted back to the point in the workflow in which they can retrieve it.

Based on the automation process, automation will address the major issues stakeholders raised regarding difficulties in accessing PA requirement information at the point of care. Providers will automatically access individual payer requirements for PA in connection with a given service and patient. This will also streamline the submission of required documentation, which will significantly reduce costs for providers and payers (the Council for Affordable Quality Healthcare [CAQH] estimates that the medical industry stands to save \$494 million annually by adopting a fully electronic PA process⁴⁰) and increase the speed with which determinations are issued, thereby reducing delays in care. In addition, automation will reduce confusion and burden associated with variation in different payers' PA requirements. While automation does not reduce the number of PAs, by removing significant process burdens, it should make PA inconspicuous to the provider in most cases.

As noted above, the final rule does not apply to commercial products. While many major commercial payers and "pay-viders" will be subject to the rule because they operate Medicare Advantage or Medi-Cal managed care plans, participants in this project expressed concern that even these payers would not implement automated processes across their fully insured plans. Stakeholders agreed that the state could play an integral role in advancing automation by extending the rule's mandate to all state-regulated payers in California. Moreover, this would provide the state with an opportunity to supplement the rule. For example, a similar stakeholder group in Massachusetts urged the state to require use of the Da Vinci Implementation Guides for the sake of consistency and coordination, while also recommending certain modifications to enhance transparency and trust.⁴¹

While automation mandates primarily affect payer activities, California stakeholders discussed the need to provide incentives to providers in terms of their adoption of fully electronic processes. At least nine states have mandated shorter time frames for PA decisions when requests are submitted electronically.⁴² Washington specifies that if a PA is submitted electronically, the response must be delivered in one calendar day for urgent requests and three calendar days for nonurgent requests.⁴³ The state requires responses in two business days and five business days for nonelectronic urgent and nonurgent requests, respectively.⁴⁴

Several additional considerations around automation may require further attention. First, the final rule addresses only automation standards for medical benefits; it does not include automation standards for prescription drugs. (Automation of prescription drug benefits is subject to the National Council for Prescription Drug Programs [NCPDP] SCRIPT standard.⁴⁵) It will be necessary to better understand how these regulations interact with the automated prescription drug PA transaction standard and ways to enable wider adoption of both methods.

Variation in payers' ability to implement automation and providers' electronic medical record (EMR) capabilities also warrant consideration. Among other things, payers will need to codify their policies and create FHIR APIs, which will likely require technical assistance. Providers must in turn rely on the Office of the National Coordinator for Health Information Technology (ONC) to release (and ultimately finalize) the HTI-2 proposed rule (HTI stands for Health Data, Technology, and Interoperability), which, among other provisions, is expected to mandate FHIR-based exchange for PA automation between providers and payers.⁴⁶ This requirement will provide the functionality that providers require to communicate with reviewers' systems from their EMRs in real time.

Finally, the final rule requires payers to adhere to specific time frames for decisions (more stringent time frames for decisions already exist in California), provide reasons for denials (California already requires this), and collect and publicly report data on the PA process and outcomes. These provisions must be implemented by January 1, 2026.

Require support of FHIR APIs as defined by the HL7 Da Vinci Project standards among providers and payers impacted by California's data sharing agreement.

Signed into law in 2021, California's data exchange framework (DxF) contains a single data sharing agreement intended to facilitate the exchange of health and social service information between California health care entities and governmental agencies to supply a complete picture of a patient's health history.⁴⁷ Impacted entities, including general acute care hospitals; physician organizations and medical groups; skilled nursing facilities that currently maintain electronic records; state-regulated payers that provide hospital, medical, or surgical coverage; clinical laboratories; and acute psychiatric hospitals, must adhere to state and federal data sharing requirements, including HIPAA (Health Insurance Portability and Accountability Act) transactions.⁴⁸ The law does not, however, require the use of FHIR APIs.⁴⁹

Project participants felt that the data sharing agreement, in combination with the recently issued final rule, would accelerate the state toward real-time clinical information sharing. In late December 2023, however, a project participant noted that signed data sharing agreements from required participants were lagging behind targeted numbers (less than 50% of required users had signed the agreement to date, though impacted entities were required to begin exchanging and providing health information before February 1, 2024); and, furthermore, that the agency lacked enforcement capabilities.

California policymakers could consider requiring providers and payers impacted by the state's data sharing agreement to support PA APIs as defined by the HL7 (Health Level Seven International) Da Vinci Project standards (i.e., those outlined and recommended within the final rule). These capabilities, in combination with the recommendation on requiring state-regulated payers to automate PA using FHIR APIs as outlined in the final rule, will work together to drive real-time payer-to-provider information exchange. Pending ONC's expected HTI-2 rule (discussed above), this requirement could serve as an additional mechanism to allow providers to participate directly in an automated PA process.

Refine Public Reporting Requirements to Promote Trust and Enable Dialogue About Additional Reforms.

California could consider adopting PA reporting requirements across all state-mandated payers and provider organizations that assume responsibility for PA processes, consistent with the metrics outlined in the CMS Interoperability and Prior Authorization final rule. Requiring organizations to report on their PA process and outcomes could increase transparency in the process and further encourage collaboration to improve PA based on meaningful data.

The final rule incorporates data collection and sharing as part of its overall effort to increase transparency in the process and allow for future reform efforts based on evidence. The rule requires impacted payers to report a list of all items and services that require PA as well as metrics on approvals, denials, approvals upon appeal, and review time frames for urgent and nonurgent PAs.⁵⁰

The state could engage a multi-stakeholder task force comprising providers, payers, patients, regulators, and policy experts to discuss whether the reporting requirements outlined in the final rule will serve all parties' objectives. Such a process could also determine whether additional reporting requirements are needed. Specifically, the state could consider the type of data and specificity with which it is reported. For example, providers and consumer advocates felt strongly that data on prescription drug ordering and PA's impact on patients should be collected. Additionally, they felt that disaggregated data would be more useful in evaluating the PA process, suggesting that data should be reported by service category — although large service categories such as behavioral health should be further disaggregated.

California policymakers could also assess reporting requirements that at least 18 other states have enacted, as many states require reporting that goes beyond what is required in the final rule.⁵¹ For example, while Washington, DC, requires plans to publicly post statistics on approvals, denials, and appeals, it also requires plans to include information on the specialties reviewing PA requests or appeals and the medical indication prompting each request, among other requirements.⁵² One consumer advocate who tracks utilization reviewers' credentials and decision outcomes was specifically in favor of enhancing reporting transparency into reviewers' credentials, suggesting that California also track and publicly share this information. (Metrics could include utilization reviewers' practice specialty, denial rates, and adherence to standards.) Furthermore, they suggested that regulators track and share more detailed information on the education programs plans are required to sponsor to ensure their reviewers are informed of the latest medical necessity and clinical requirements.

Extend the Duration and Scope of PA Approval for Ongoing Care with a Defined and Accepted Course of Treatment.

California could consider expanding the duration and scope of a PA to limit the need for multiple PAs for a course of care unlikely to be significantly altered. Many stakeholders participating in this project favored this idea for certain chronic conditions with well-defined treatment pathways and certain types of mental health and SUD treatments.

In connection with the perception that there are "too many" PAs, the use of PA for ongoing treatment of chronic conditions seemed particularly objectionable for both the providers and consumer advocates who participated in this project. Several potential solutions for consideration that have been tested or implemented in other states to minimize the use of PA in connection with chronic conditions and/or care circumscribed by evidence-based protocols are described below. Because the solutions sometimes rely on terms that are difficult to define and are subject to justified differences in judgment, further discussion among diverse stakeholders (including providers, payers, consumer advocates, and medical specialty societies, as well as policy experts) is needed before crafting specific policies. Evidence from states that have implemented similar solutions could be useful in this endeavor.

Extend the period for which a PA is effective for conditions with well-defined courses of treatment.

California stakeholders expressed interest in a solution that would extend the duration of PA approval for certain types of care with well-known treatment courses (also known as "proactive authorization"), such as for certain chronic conditions and medications.

Several other states have implemented reforms along this line. In 2023, Montana updated its laws to prevent insurers from applying PA when "a covered person has been prescribed the covered drug at the same quantity without interruption for [six] months."⁵³ States have also specifically addressed the duration of PA approvals for chronic conditions. Illinois specifies that an approval "for a recurring health care service or maintenance medication for the treatment of a chronic or a long-term condition" must remain valid for 12 months or the length of the treatment as decided by the provider — whichever is shorter.⁵⁴ Washington, DC, also requires approvals for chronic conditions to remain valid for "as long as reasonable and necessary to avoid disruptions in care."⁵⁵

There are technology solutions to facilitate greater ease with which to authorize a full course of treatment (see sidebar). An automated solution may prove easier to test once California has invested in the push to automate PA. This solution could be reconsidered once the technology is in place to evaluate the benefits it can produce, such as fewer PAs and more real-time decisions, which should further reduce delays in care. In the meantime, there may still be ways to define and implement an authorization for a full course of treatment using current processes.

Cohere Health, a health technology vendor, created an automated solution by codifying the American Academy of Orthopaedic Surgeons Clinical Practice Guidelines for musculoskeletal care and incorporating both artificial intelligence and machine learning to allow providers to obtain one prior authorization (PA) approval for a full treatment course. Humana tested this solution in a dozen states; pilot results included a median approval time of zero minutes and showed that 95% of PAs for musculoskeletal care were processed using the solution.⁵⁶

Stakeholders suggested that certain maintenance drugs, such as statins, could be appropriate candidates for this type of solution. This solution could eliminate PAs for care pathways that are clinically proven, thereby decreasing potential delays in care for patients and removing the associated burden and costs providers and payers may experience by repeating the process for treatments that have not changed

Although a number of California stakeholders favored this solution, most insisted that it be designed in a way that preserves checkpoints between the provider and the patient; there must be an opportunity for the provider to converse with the patient and notify them of potential treatment alternatives. Likewise, the provider or patient could hold the responsibility to notify the payer of a material change in the patient's condition or care plan to ensure the prescribed treatment remains appropriate. In addition, in the case of prescribed medications, the provider should confirm that the patient is still engaged in the given course of treatment. A checkpoint could ensure that costs associated with the treatment are not wasteful (i.e., confirm that a pharmacy is not automatically dispensing and delivering medications or devices the patient is no longer using).

Extend the period for which a PA is effective during insurance transitions.

To avoid unnecessary disruptions in care, several states have enacted provisions prohibiting the imposition of PA for ongoing treatment when a patient changes insurance plans, voluntarily or otherwise. The prohibition can extend from 30 to 90 days after the new coverage takes effect.⁵⁷ For example, Minnesota requires that a patient's new plan honor a PA for the first 60 days of coverage with the requirement that the provider or patient submit evidence that their previous PA was approved.⁵⁸ California's Medi-Cal program specifies that members with an active prior treatment authorization who are forced to transition from a fee-for-service plan to a managed care plan are eligible to continue the treatment for 90 days under the new plan.59

This solution is a relatively straightforward way to eliminate sudden disruptions in care unrelated to reviews of the continued appropriateness of the patient's care plan. The provision maintains an insurer's right to review the patient's benefit terms and ongoing need for care, if necessary, while allowing both the provider and patient to clarify the ongoing need for care. This solution had support from several stakeholders. (See Tables A1 and A3 in Appendix A.)

Extend the scope of a PA approval for a group of codes.

More general efforts to limit the number of PAs include issuing approvals for a "family" of procedure codes. This approach is described in a previous NEHI report that included recommendations for streamlining the PA process in Massachusetts.⁶⁰ Some Massachusetts providers expressed frustration in instances when they received approval for a particular device or procedure and, upon realizing during the procedure that they required a different — yet related — device or procedure, received a denial for the related Current Procedural Terminology (CPT) code. Providers favored a solution that would encompass working with payers to group certain CPT codes into families; approval for a code within a family would encompass approval for other codes within that family. This type of solution could work well in a service area such as radiology (e.g., allowing a provider to order an MRI with or without contrast) and would reduce costs associated with additional PA submissions and avoid delays in care.

Considering a Gold-Carding Program

Stakeholders participating in this project also discussed "gold-carding" as a potential solution to reduce the frequency of prior authorizations (PAs). California policymakers are currently considering a proposal that would require payers to implement a PA exemption process for physicians who demonstrated a ≥90% approval rate for most services and brand-name prescription drugs subject to PA during the previous yearlong contract period.⁶¹ This proposal would also require payers to establish an electronic PA process and track their annual approval, denial, and appeal rates to remove PA from the products and services with a ≥95% approval rate.⁶² Six other states have established gold-carding programs, though limited data on results are available as most of these policies were recently established. Vermont released pilot results from a multiyear gold-carding program for specific services. In particular, BlueCross BlueShield of Vermont reported on its "provider passport" program for advanced imaging, for which specialists and primary care physicians were eligible. The plan found an increase in utilization among exempt providers compared with their baseline utilization patterns, which they noted increased the "pressure" on premiums.⁶³ Texas also passed a gold-carding law in 2021, though reports continue to highlight implementation issues. The Texas Medical Association reported in December 2023 that only 3% of providers had been gold-carded, due to strict guidelines around eligibility.⁶⁴

The majority of interviewees and Advisory Committee members agreed that pursuing a gold-carding program would not adequately alleviate the issues they flagged. For example, participants expressed concern that evaluating providers' performances based solely on their overall PA approval rate for a particular insurer may not provide an accurate measure for — or picture of — their adherence to prescribing medically appropriate care. Some stakeholders were concerned about removing PA requirements from services, drugs, or devices with 95% approval rates at the end of the year; they argued that the criteria used to determine the appropriateness of PA requirements should not be restricted to approval rates.

Gold-carding programs are also difficult to administer, as noted above. Providers must receive exemptions for each plan with which they contract, which may cause more confusion surrounding PA requirements if the provider serves patients covered by multiple plans. Plans must in turn audit providers' performances and are often required to reach out to providers to inform them that they qualify for an exemption; this process creates additional burden for the plan.

Develop Transparent Principles for the Annual Review of PA Requirements.

California policymakers could require payers to review the application of PA to medical services and prescription drugs annually, similar to the state's current provision mandating that payers update their medical necessity criteria. Given that most California payers annually review their PA requirements for effectiveness and issue updates as needed, an annual review mandate would clarify this practice standard without adding additional burden to payers.

However, because the annual review process is relatively opaque, some stakeholders also favored requiring payers to publish the principles on which their reviews are based. There was agreement that having insight into the process (i.e., the criteria by which payers evaluate whether to retain or remove services subject to PA) would enhance transparency and trust in the process while allowing payers to retain autonomy over the principles they employ. Access to payers' review principles could also provide regulators and stakeholders with insights into the utility of the review process.

Conclusion

PA reform efforts must continue to balance the benefits that PA provides with the pain points experienced by providers, payers, and patients. The potential process improvement approaches described here are based on efforts to advance reform proposals that target priority issues. All must be tailored to California's unique health care market, and those pushing for reform must continue to gather input from diverse stakeholders. Only by working across sectors can they both enhance understanding of the issues and increase the likelihood that reforms will succeed.

Appendix A. Study Design and Participants

The authors first performed a literature scan on prior authorization (PA) and reform efforts over the past decade. Sources included peer-reviewed publications, trade publications (i.e., articles and reports published by organizations or the government), and state and federal legislation. The review excluded non-US-based publications. Stakeholder findings in this report were supplemented with those identified throughout the literature scan. A more detailed summary is available in the authors' November 2023 interim report titled, *Paths Forward on Prior Authorization: Exploring Reforms in California*.⁴

Reliance on a multi-stakeholder Advisory Committee was critical to this work. The committee provided guidance and feedback relevant to the authors' findings. Advisory Committee members were not asked to endorse the final recommendations proposed in this report, either individually or on behalf of their organization.

ORGANIZATION	NUMBER OF REPRESENTATIVES	STAKEHOLDER TYPE
Individual contributor	1	Policy expert
Health Access California	1	Consumer advocate
The Kennedy Forum	1	Consumer advocate
Cedars-Sinai	2	Hospital
Children's Hospital Los Angeles (CHLA)	1	Hospital
Dignity Health Medical Foundation (CommonSpirit Health)	1	Medical group
Hill Physicians Medical Group	1	Medical group
Sharp Rees-Stealy Medical Group	1	Medical group
Blue Shield of California	1	Payer
Elevance Health (Anthem)	1	Payer

Table A1. Advisory Committee

The authors developed and disseminated three surveys based on stakeholder type. The surveys contained questions to assess respondents' a) use of PA and its impact, b) views on PA application and efficacy, and c) views on major PA reforms. The surveys were intended to supplement interview findings by gathering feedback from a wider range of California stakeholders.

Overall, the surveys suffered poor response rates (i.e., 37.5%, 0%, and 28.6% completed response rates among surveyed providers, consumer advocates, and payers, respectively). Some recipients explicitly declined to participate while others did not respond to the survey request. A few confirmed that they would complete the survey but failed to do so.

Table A2. Survey Recipients

ORGANIZATION	STAKEHOLDER TYPE	
California Chronic Care Coalition	Consumer advocate	
Health Access California	Consumer advocate	
Steinberg Institute	Consumer advocate	
The Kennedy Forum	Consumer advocate	
Blue Shield of California	Payer	
Aetna CVS Health	Payer	
Elevance Health (Anthem)	Payer	
Inland Empire Health Plan	Payer	
Kaiser Permanente	Payer	
Partnership HealthPlan	Payer	
SCAN Health Plan	Payer	
Cedars-Sinai	Provider/hospital system	
Children's Hospital Los Angeles (CHLA)	Provider/hospital system	
Dignity Health Medical Foundation (CommonSpirit Health)	Provider/hospital system	
Hill Physicians Medical Group	Provider/hospital system	
Sharp Rees-Stealy Medical Group	Provider/hospital system	
Stanford Health Care	Provider/hospital system	
UCLA Hospital System	Provider/hospital system	
UCSF Health	Provider/hospital system	

The authors conducted 45- 60-minute interviews with 16 California stakeholders. The purpose of the interviews was to assess stakeholder views on the benefits and issues associated with the PA process and potential reform efforts the state should consider. Specifically, interview questions sought to elicit a) whether PA is an "issue" in California and to what extent; b) whether existing reforms address the issues flagged by payers, providers, and patients; and c) additional ideas to reform the PA process. (See Appendix B for a list of interview questions.)

Table A3. Interviewees

ORGANIZATIONAL AFFILIATION	STAKEHOLDER TYPE
Los Angeles General Medical Center; National Multiple Sclerosis Society	Consumer advocate
Psych Appeal	Consumer advocate
Central California Alliance for Health	Payer
Cigna Healthcare	Payer
San Francisco Health Plan	Payer
California Health Benefits Review Program (CHBRP)	Policy expert
UC Berkeley	Policy expert
A private pediatric practice in Orange County	Provider/hospital system
California Hospital Association	Provider/hospital system
Hill Physicians Medical Group	Provider/hospital system
MemorialCare Medical Foundation	Provider/hospital system
Sutter Medical Foundation	Provider/hospital system
Center for Data Insights and Innovation (CDII)	Regulatory agency
California Department of Insurance (CDI)	Regulatory agency
California Department of Health Care Services (DHCS)	Regulatory agency
California Department of Managed Health Care (DMHC)	Regulatory agency

Appendix B. Interview Questions

Our Introduction

Who we are; the study we're conducting; our definition of prior authorization.

Identification

- 1. Please tell us about your current role and your tenure in the position.
- 2. How would you describe your organization in the context of the California health care landscape?
- 3. Are there other positions you have held that influence your views on prior authorization?

Experience

- 1. What is your experience with prior authorization?
- 2. For providers and payers: Can you characterize the types of services and benefits to which prior authorization most often applies (e.g., specialty outpatient prescription drugs, high-cost imaging, inpatient care, etc.)?
- 3. How does prior authorization affect you or your organization on a daily basis (if at all)?
 - a. If you consider prior authorization to be a burden in some (or all) cases, how do you define that burden (i.e., is it costly; does its application require resources that could be used more effectively elsewhere; does it cause delays in patient care)?
 - b. Are there examples of the application of prior authorization that highlight its benefits?
- 4. For payers: How do you determine whether a medical or pharmaceutical service/treatment is subject to (or should be subject to) prior authorization?
 - a. Do you approach the decision differently for medical versus pharmaceutical services?
 - b. For approximately what percentage of services do you require prior authorization?
 - i. Does your response change if we ask what percentage of the most frequently utilized services require prior authorization? Do you have a way of monitoring the frequency of prior authorization requests? Or trends in prior authorization requests?
 - ii. What process do you use to review prior authorization requirements?
 - iii. What prior authorization requirements generate the greatest benefits? What are these benefits?
 - iv. What prior authorization requirements are most costly to administer?
 - v. What factors do you consider in deciding to retire a prior authorization requirement?
- 5. For providers: Tell us the process you use to obtain external prior authorization approvals, including submission of a request and receipt of a response.
 - a. Do you apply any form of prior authorization internally? How do you do so, and how do you decide what services will be subject to prior authorization?

Reforms/Changes

- 1. When considering the current prior authorization process, what challenges are you most interested in addressing? How would you quantify those challenges?
- 2. Do you have experience with efforts to reform prior authorization (e.g., gold-carding programs), policies, or other initiatives (e.g., automation)?
 - a. Which reform efforts address what you perceive to be the most significant challenges with prior authorization?
 - b. Did you or your organization collect feedback on the efforts from other individuals involved (e.g., other providers, payers, patients, etc.)?
 - c. What is the current status of each effort?
- 3. Are there any other reforms you are interested in but do not have experience with?
 - a. If yes, what are they?
 - b. How do you think the reforms will improve the prior authorization process?
- 4. Do you have concerns about the impact of these reform efforts on patient access to care?
- 5. What are two or three prior authorization reforms you are most interested in pursuing? Why?
- 6. What are two or three prior authorization reforms you are *least interested* in pursuing? Why?
- 7. In thinking about your entire list of priorities, where does reforming prior authorization fall?
 - a. In thinking about your organization's entire list of priorities, where does reforming prior authorization fall?

Final Thoughts

- 1. Do you think there are other ways to meet the objectives of prior authorization? If so, can you describe these?
- 2. Is there anything else you would like to share with us?

Appendix C. Additional Issues Related to Prior Authorization

Project participants identified numerous issues related to the prior authorization (PA) process. This paper focuses on the five highest-priority ones. Listed here are five additional issues that future multi-stakeholder collaborators may wish to examine.

The requirement to publish and update drug formularies does not always have the intended effect of supplying the provider and patient with accurate and up-to-date information at the time of care. California requires health plans that provide prescription drug benefits to post and maintain their formularies on their websites so that the public can access them. Formularies must follow a standardized template that includes information on (a) cost sharing and utilization management, (b) any preferred drugs, (c) medication tiers, and (d) other relevant information.⁶⁵ Despite this, some provider stakeholders noted that drug formularies do not provide sufficient or accurate information that can assist treatment decision-making at the point of care. Using the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard to automate the prescription drug PA process should provide up-to-date PA information at the point of care. Additional efforts to expand use of the SCRIPT standard should be considered.

There is no clear way to signal to providers/their staff during the PA process that the request documentation is incomplete without issuing a denial. One payer stakeholder specified that a PA submission that does not include complete documentation often prompts a denial, when in fact, there is a need for more information. Nevertheless, a denial in this instance prompts the adjudication process through a peer-to-peer conversation, via appeal, or by another means. The authors address this issue by recommending automating PA. Monitoring the rate of denials in conjunction with the implementation of automated processes will be important in determining whether automation was able to reduce denials based on incomplete information. The reasons for PA denials are unclear. Although California requires state-regulated plans and reviewer organizations to "include a clear and concise explanation of the reasons for the plan's decision, a description of the criteria or guidelines used, and the clinical reasons for the decisions regarding medical necessity,"⁶⁶ some provider stakeholders noted that PA denials do not always include a clear reason for the decision. Some also reported difficulty in contacting the responsible utilization management (UM) reviewer to discuss or appeal a decision. The authors had insufficient information to understand the scope of this issue.

The process for appealing a denial is not clear and/or the appeals process is complex. PA denials must also include a description of how the enrollee can appeal a decision.⁶⁷ Even so, some state regulators and consumer advocates noted that this information is often buried in paperwork and not easily accessible to enrollees. The authors had insufficient information to understand the scope of this issue, which would also seem best addressed through ongoing education by state regulators and consumer advocates.

Prior authorization is utilized "unevenly" across mental health and SUD services. Despite the Mental Health Parity and Addiction Equity Act (MHPAEA), which requires (a) that mental health and substance use disorder (SUD) conditions be covered and (b) that coverage requirements be "no more restrictive than insurance coverage for other medical conditions,"⁶⁸ consumer advocates perceive issues related to PA use among mental health and SUD services, citing its use as stringent compared with that required for other medical conditions. In addition, PA requirements are perceived to be applied more stringently for SUD treatment than for mental health services. While the authors recognize that developing data on this issue is complicated, they encourage discussion of data reporting requirements that would offer insights that anecdotal evidence cannot provide.

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- 65. <u>California Health and Safety Code § 1367.205.</u>; and <u>California</u> <u>Insurance Code § 10123.192.</u>
- 66. California Health and Safety Code § 1367.01.; and California Insurance Code § 10123.135.
- 67. California Health and Safety Code § 1367.01.; and California Insurance Code § 10123.135.
- **68.** "<u>Mental Health Parity</u>," American Psychiatric Association, accessed May 23, 2024.