March 13, 2023

Submitted via regulations.gov

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-8016

Re: RIN 0938–AU87
Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Dear Administrator Brooks-LaSure:

The National Health Law Program (NHeLP) is a public interest organization working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to provide these comments on the Department of Health and Human Services' (HHS) proposed rule on prior authorization and interoperability in Medicaid, the Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs) sold through the Affordable Care Act (ACA) Marketplaces (hereinafter "Prior Authorization

Proposed Rule").[1] Also note that, while our comments focus primarily on Medicaid, which has robust protections for enrollees, our prior authorization concerns and proposals should also apply to Medicare Advantage plans, Qualified Health Plans (QHPs), and the Children's Health Insurance Program (CHIP), unless otherwise indicated.

1. **Prior authorization often imposes an undue barrier to medically necessary care**

We welcome HHS's efforts to streamline and facilitate processing of prior authorization requests. The Prior Authorization Proposed Rule is an important first step in bringing greater accountability to prior authorization through transparency and data reporting. We urge HHS to go further in future regulatory action to curb the abuse of prior authorization as a cost savings strategy that endangers patients' health.[2]

Insurers often use prior authorization to unreasonably and unlawfully deny medically necessary care. For example, a survey from the American Medical Association found that eighty-two percent of physicians reported that patients abandoned needed treatment because of prior authorization burden and delays.[3] Investigative reporters from *Pro Publica* recently published an exposé on United Healthcare, revealing arbitrary denials of care and a quixotic effort to obtain life-changing medication by a chronically ill young student, labelled by the

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[1] U.S. Dept. of Health & Human Srvs., *Proposed Rule - Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program,* 87 Fed. Reg. 76238 – 76371 (Dec. 13, 2022), https://www.govinfo.gov/content/pkg/FR-2022-12-13/pdf/2022-26479.pdf.

[2] In these comments, we use the term "patient" and "enrollee" interchangeably, recognizing that HHS largely uses the term "patient" in the Prior Authorization Proposed Rule. We note, however, that individuals who need health care services, including those with serious or chronic health conditions, may not necessarily identify themselves as patients. See, *e.g.*, *The Denver Principles* (1983), "We condemn attempts to label us as "victims," a term which implies defeat, and we are only occasionally "patients," a term which implies passivity, helplessness, and dependence upon the care of others. We are people with AIDS,"
https://data.unaids.org/pub/externaldocument/2007/gipa1983denverprinciples_en.pdf.

[3] American Medical Assoc., *2021 AMA prior authorization (PA) physician survey* (2022), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

insurer as high cost.[4] A *Washington Post* health and science reporter recounted her own experience jumping through prior authorization hoops to obtain a medication for her three year old child diagnosed with juvenile idiopathic arthritis, a chronic immune disorder that, untreated, could lead to disabling joint damage.[5] The burden of prior authorization processes disproportionately affects people of color and underserved communities. For example, providers treating African American communities for cardiovascular disease are often smaller practices with fewer resources, increasing the burden of prior authorization and exacerbating health disparities.[6] Another study documented regional differences in prior authorization for PreExposure Prophylaxis (PrEP), creating undue barriers to potentially life-saving HIV prevention in regions hardest hit by the pandemic.[7]

For some insurers, creating barriers and denying care is an effective business model designed to maximize revenue, where patients and providers get worn down amid seemingly endless reviews and documentation requests. The insurers are winning, too. According to a survey by the Kaiser Family Foundation, in QHPs sold through HealthCare.gov, consumers appealed less than two-tenths of one percent of denied in-network claims, and insurers upheld fifty-nine percent of denials on appeal.[8] Another study found that Medicare Advantage plans denied two million prior authorization request, yet enrollees appealed only eleven percent of those denials.[9] Data on prior authorization and claims denials is even more scarce in Medicaid

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[4] David Armstrong, et al., *UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings*, Pro Publica (Feb. 2, 2023), https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis.

[5] Carolyn Y. Johnson*, I wrote about high-priced drugs for years. Then my toddler needed one.*, WASH POST (Jan. 3, 2023), https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/.

[6] Assoc. of Black Cardiologists, *Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients* (Winter, 2019), http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf.

[7] Kathleen A. McManuset al., *Regional Disparities in Qualified Health Plans' Prior Authorization Requirements for HIV Pre-exposure Prophylaxis in the United States*, JAMA NETW OPEN (Jun. 3, 2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766669.

[8] Karen Pollitz et al., *Claims Denials and Appeals in ACA Marketplace Plans in 2021*, Kaiser Fam. Found. (Feb. 9, 2023), https://www.kff.org/private-insurance/issue-brief/claims-denials-and-appeals-in-aca-marketplace-plans/.

[9] Jeannie Fuglesten Biniek & Nolan Sroczynski*, Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021*, Kaiser Fam. Found. (Fed. 2, 2023), https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/?utm_campaign=KFF-2023-Medicare&utm_medium=email&_hsmi=244325042&_hsenc=p2ANqtz-

managed care, where only a small handful of states publicly report information on denials and appeals.[10]

The HHS Office of Inspector General (OIG) is currently investigating the extent of Medicaid prior authorization denials, as well as auditing certain managed care organizations (MCOs) for compliance with federal and state requirements when denying access to care that required prior authorization.[11]

One recently completed review found consistent use of prior authorization to deny medically necessary care. The HHS OIG report on Keystone First—Pennsylvania's largest Medicaid MCO—found noncompliance with federal and state requirements in 76 of 100 denied service requests that required prior authorization.[12] In several cases, the MCO completely denied pediatric overnight skilled nursing services based on irrelevant information.[13] As the OIG report noted, these denials can place the health and safety of the Medicaid enrollee at risk, as their caregiver may be unavailable overnight. In another instance, Keystone First denied pediatric skilled nursing services for a beneficiary with encephalitis, hyper immunodeficiency, autoimmune hemolytic anemia, spastic quadriplegia, seizure disorder, and several other complex conditions.[14] The child had a single caregiver, whose responsibilities included respiratory treatments, chest physiotherapy, and frequently repositioning the beneficiary's head to maintain their airway. Yet Keystone inexplicably denied the request as not medically necessary.

95MmRl8bjGH1WPz9_iUlYwKzW2q_vSwBfK5b8wRyh7l9nbHkuwja5LjJNejE41JrdsxK310FKSUXiSFQi7rrQCqt_Jcg&utm_content=244325042&utm_source=hs_email.

[10] Lesley Baseman & Amy Zettle, *Medicaid & CHIP Payment & Access Comm'n, Denials and Appeals in Medicaid Managed Care* (Jan. 26, 2023), https://www.macpac.gov/wp-content/uploads/2023/01/10_Denials-and-appeals-in-Medicaid-managed-care.pdf.

[11] *Id.*; U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *Prior Authorization Denials in Medicaid Managed Care*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000387.asp.

[12] Dep't of Health & Human Servs., Office of Inspector Gen., *Keystone First Should Improve Its Procedures for Reviewing Service Requests That Require Prior Authorization* 5 (2022), https://oig.hhs.gov/oas/reports/region3/32000201.pdf.

[13] *Id.* at 6.

[14] *Id.* at 7-8.

Keystone also failed to properly notify beneficiaries of their right to request a state fair hearing after exhausting the MCO's appeal process in 72 of 100 denied service requests.[15] Such information is vital for enrollees to understand their rights in Medicaid MCOs.

These studies and personal accounts represent just a small fraction of evidence showing how health insurers overuse and abuse prior authorization to the detriment of patient health.

NHeLP strongly supports HHS's proposals to streamline and bring greater transparency to prior authorization policies, processes, and outcomes. The Prior Authorization Proposed Rule builds upon HHS's earlier efforts to curb insurance company abuses through discriminatory benefit design. Most recently in the Notice of Benefit and Payment Parameters Rule for 2023, HHS strengthen nondiscrimination protections for plans subject to Essential Health Benefits (EHB) coverage requirements, clarifying that "a non-discriminatory benefit design that provides EHB is one that is clinically-based."[16] In comments, we showed how health insurers routinely and unlawfully discriminate against persons with disabilities or chronic conditions through prior authorization.[17] In the Prior Authorization Proposed Rule, we urge HHS to take additional steps to further to protect patients from egregious insurer practices. HHS should ensure that prior authorization criteria are clinically-based and based on the generally accepted standard of care. Insurers should give great weight to the medical judgment of the treating provider, who is best positioned to determine what is medically appropriate for a particular patient.

A key component of identifying and deterring discriminatory design is transparency, which includes the underlying data, standards, and other factors used in prior authorization

[15] *Id.* at 9-10.
[16] U.S. Dept. of Health & Human Srvs., *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023 Final Rule*, 87 Fed. Reg. 27208, 27390 (May 6, 2022), *codified at* 45 C.F.R. § 156.125(a), https://www.govinfo.gov/content/pkg/FR-2022-05-06/pdf/2022-09438.pdf.
[17] Natl. Health Law Program, *NHeLP Comments on HHS Notice of Benefit and Payment Parameters for 2023* (Jan. 27, 2022) at 20, https://healthlaw.org/resource/nhelp-comments-on-2023-notice-of-benefit-and-payment-parameters-proposed-rule/.

decisions.[18] Although disclosure under mental health parity has not yet reached its promise, the impact of greater transparency has shown itself in the cases enforcing parity.[19]

As discussed more fully below, health care consumers, researchers, and advocates should have ready access to plan information, including: the services are subject to prior authorization; criteria used for prior authorization decisions, and data on approvals, denials, appeals, and reversal rates. Greater transparency in prior authorization criteria will help deter arbitrary and discriminatory coverage denials. Moreover, this information should be available to enrollees and potential enrollees at the time of plan selection.

The relationship between a patient and a health insurance company is decidedly lopsided. Plan selection is the one moment in which health care consumers have any power when facing the multi-billion dollar health insurer juggernaut. Consumers, especially those with chronic conditions, often conduct extensive research when choosing a plan, evaluating key plan design features such as cost sharing, prescription drug formularies, and provider network networks. To make a truly informed decision when selecting a plan, consumers should be able to easily access information on the plan's prior authorization policies, including which services are subject to prior authorization, response times, denial rates, and the criteria plans use when making medical necessity determinations. The harsh spotlight of public disclosure and greater transparency will deter insurers from arbitrary coverage denials, which, under the current regulatory and enforcement framework, continues unchecked.

We urge HHS to take additional steps to help patients avoid unnecessary and harmful disruptions in medical treatment. The Prior Authorization Proposed Rule would require payer-to-payer Application Programming Interface (API), with enrollee consent requirements so that a patient's medical record, utilization data, and prior authorization documentation can follow an

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[18] *See* Elizabeth Edwards et al., Nat'l Health Law Program, *NHeLP AHRQ Comments* (June 10, 2021), https://healthlaw.org/resource/nhelp-ahrq-comments/ (regarding the need for transparency in assessment tools, guidelines, and other health care tools); NHeLP et al., Amicus Brief in *N.R. v. Raytheon*, https://healthlaw.org/resource/amicus-n-r-v-raytheon-company-u-s-court-of-appeals-first-circuit/ (discussing the important function of mental health parity disclosure requirements and the challenges with enforcing that requirement).

[19] See, e.g., *Wit v. United Behavioral Healthcare*, 14-cv-2346-JCS, 2019 WL 1033730 (N.D. Cal. July, 27, 2020) (finding parity compliance issues with utilization management tools that used criteria that did not align with clinically accepted criteria and was unduly influenced by fiscal rationales); *see also* NHeLP et al., Amicus Brief in *Wit v. United Health Care,* https://healthlaw.org/nhelp-files-friend-of-court-brief-to-protect-access-to-promised-behavioral-health-care/.

enrollee when an enrollee changes health plans. We support this proposal. However, HHS should go a step further, and require plans to honor other plans' prior authorization approvals.

Currently, patients often have to jump through hoops to obtain new approvals for long-standing treatment regimens when they change plans. Insurers also compel patients to start anew with step therapy, where they must try and fail on a prescription drug or other medical intervention before obtaining insurer approval. In managing HIV, physicians tailor anti-retroviral therapy for patients by individualizing optimal treatment combinations.[20] If that information follows a patient when they change plans, the approvals should follow too. Gaps in treatment can have deadly consequences for some, including people living with HIV/AIDS where "even short interruptions of care can threaten health and undermine prevention effects."[21]

Prior authorization requirements often put patients at risk, particularly those facing serious health challenges who change health plans and need to fight with their insurers to obtain approval, even for long-standing, effective treatment.

HHS has ample authority to reign in insurer excesses in prior authorization. It should do so.

2. Facilitate prior authorization processing and data access

While we are skeptical of prior authorization's value as a utilization management and care coordination tool, we agree with HHS that the process should be as transparent, efficient, and simple as possible to ensure it does not cause unnecessary delay or wrongful denials. We generally support proposals to include prior authorization information in the beneficiary API as close to real time as possible. We urge HHS to ensure that enough information and supporting documentation is included in the API so beneficiaries can understand the process, the timing, and most importantly, the justifications for any decisions and the steps they need to take if they would like to appeal that decision.

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[20] See *Formulary Decision-Making Challenges in HIV*, AM. J. MANAGED CARE (March 19, 2018), https://www.ajmc.com/peer-exchange/special-considerations-in-hiv-management/formulary-decisionmaking-challenges-in-hiv.

[21] *See Drug Resistance*, AIDS INFO (Jan. 28, 2019), https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/56/drug-resistance; Dana P. Goldman, et al., *The Prospect Of A Generation Free Of HIV May Be Within Reach If The Right Policy Decisions Are Made*, 33 *Health Affairs*, 430 (2014).

§ 431.60 Beneficiary access to and exchange of data

HHS should strengthen requirements to help ensure that enrollees (and their providers) can access and evaluate prior authorization information. First, while we support the requirement that any adjudicated authorization decision should specify the reason, which must be based on ascertainable standards that include sufficient supporting documentation to understand the basis for reaching that decision.[22] Enrollees and their providers will often need supporting documentation, including clinical criteria, to understand and evaluate the basis for the decision. If a payer denies a prior authorization for not being "medical necessary," for example, the API should also make available documentation explaining the clinical basis for that decision. Without that information, an enrollee may have no way to evaluate if the decision was in error and should be appealed.

Second, we think the information listed in (b)(5)(i) should require the API to include basic instructions and contact information to inform an individual how to challenge the decision or report delays in processing requests. While streamlining the API data promises to substantially reduce delays in informing enrollees about important coverage authorization decisions, this also means that a health care portal may well be the first place they receive notice about these decisions. They should have immediate access to the justifications for any coverage denial as well as the steps they need to take to challenge that decision. We do not suggest that the API should replace formal notice and due process requirements according to Medicaid law and policy, but rather that it would provide another avenue – and perhaps a faster one -- for individuals to know how to challenge a decision by appropriate rules for the relevant payer.[23]

Third, the standard for posting this information to the API should be accelerated for expedited prior authorization requests. HHS proposed at § 438.210 that such requests in managed care should take no more than seventy-two hours, or less if a state sets a lower limit. If a payer makes a decision on the Friday before a long weekend, the next business day would be four days later, which would make it harder for that individual to find information on the decision, and whether the enrollee should challenge the decision. We suggest that expedited prior authorization requests should meet a higher timeliness standard. Changes in status on such

[22] Jane Perkins, *Demanding Ascertainable Standards: Medicaid as a Case Study*, CLEARINGHOUSE REV. (2016), https://healthlaw.org/resource/demanding-ascertainable-standards-medicaid-as-a-case-study/.

[23] See discussion on Medicaid due process in Section 3, below.

requests should be made available through the API within twenty-four hours. This shift in timeline should also apply to the provider and payer-to-payer APIs described in § 431.61.

Finally, reporting of the aggregate data API utilization at proposed § 431.60(h) will provide a hazy picture of how widespread the use of health apps and patient portals in the Medicaid population is and how actively beneficiaries engage with their health data electronically. We support beginning to track this information to gauge the effectiveness of APIs at streamlining the prior authorization process, but we do not think the two listed data points go far enough. States will have nearly three years to implement this rule and will likely have to substantially revamp both state and plan data infrastructure to comply, but once they have done so there will be little incentive to go back and add new capacity a few years later. We therefore very strongly encourage HHS to require states in the final regulation to require the new APIs to have the capacity to track and report the frequency of beneficiary data transfers by key demographic features – such as race, ethnicity, preferred language, disability, sex, sexual orientation, gender identity, income, and geographic area – not just in the aggregate.

We suspect that use and uptake of these health apps will be uneven across some of these communities – particularly for people with Limited English Proficiency (LEP) and people with disabilities who may encounter accessibility barriers. Building in the capacity to track and report this data at a more granular level could provide important insights about equitable access and help to target future outreach more effectively.

§ 431.61 Access to and exchange of health data to providers and payers

We are concerned that the proposed exemption process will leave some Fee For Service (FFS) Medicaid populations – groups which include a disproportionate share of people with disabilities – without comparable access to any benefits derived from streamlining the prior authorization process with beneficiary, provider, and payer-to-payer APIs. While we recognize the potential challenges of developing and maintaining the necessary data infrastructure for a relatively small FFS population, we think this exemption creates an unfair, two-tiered system that may leave behind people with disabilities who already face high barriers to care posed by the administrative burdens and uncertainties that prior authorization can cause. In many states, people receiving Home and Community Based Services (HCBS) through waivers that are carved out of managed care and may be exactly the individuals who would fall under the exemption and fail to benefit from the streamlined process in this regulation.

As of 2020 (the most recent available information), eight states had small FFS Medicaid populations that totaled just under ten percent of all Medicaid beneficiaries.[24] Several others were within two or three percent of the ten percent exemption threshold. As these numbers fluctuate from year to year, states on either side of this arbitrary threshold may cross back and forth, leading to uncertainty about whether their exemption would continue. We foresee the possibility that states near the threshold may force people into managed care based solely on their desire to seek or maintain a FFS exemption to avoid the expense of creating new API data infrastructure. Half of all states had comprehensive managed care penetration rates exceeding eighty percent in 2020 that put them in range of this exemption threshold.[25]

Several large states (TX, PA, NJ, VA) are among the states that currently would likely qualify for an exemption. Even if the relative percentage of FFS beneficiaries is relatively small in these states, the total number of FFS beneficiaries who fall in the exception exceeds the entire Medicaid population of some smaller states. For example, based on 2020 enrollment, Texas would have roughly 216,000 beneficiaries in FFS for whom it would not be required to make prior authorization information available via the APIs.[26] But Kansas, which sits just below the threshold at eighty-eight percent would have to develop API infrastructure for all of its 48,000 FFS enrollees.[27]

States should receive a ninety percent federal match to update their computer systems to implement this API infrastructure, and the process projects to save ten to twenty billion dollars in administrative costs over the first decade.[28] We strongly recommend that HHS finalize regulations that require states to make these new APIs available to every Medicaid beneficiary without exemption, regardless of their care delivery system. States may need extra time to implement the system for smaller populations in FFS, though HHS could provide extensions similar to the one contemplated in § 431.61(c)(1), as long as states justify the need for more

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[24] Kaiser Family Found., *Total Medicaid MCO Enrollment 2020* (last visited Mar. 4, 2023), https://www.kff.org/other/state-indicator/total-medicaid-mco-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Percent%20of%20State%20Medicaid%20Enrollment%22,%22sort%22:%22desc%22%7D.
[25] *Id*.
[26] CMS, *Managed Care Enrollment by Program and Population 2020* (last visited Mar. 3, 2023), https://data.medicaid.gov/dataset/e2ce0d2f-07c5-5213-947a-31e19bc649f6/data?conditions%5b0%5d%5bresource%5d=t&conditions%5b0%5d%5bproperty%5d=year&conditions%5b0%5d%5bvalue%5d=2020&conditions%5b0%5d%5boperator%5d==.
[27] *Id.*
[28] 87 Fed. Reg. 76351.

time and require milestones to achieve compliance. We strongly believe that the regulation should not create loopholes that allow for substantial semi-permanent exemptions from implementing the API system, as this could lead to a two-tiered Medicaid system where individuals left in small state FFS programs have lower timeliness and access standards.

If HHS does not agree to require states to make prior authorization APIs available to all FFS Medicaid beneficiaries, we recommend that the current threshold be increased to at least ninety-five percent of all beneficiaries in comprehensive managed care and that states would also have an absolute threshold, such as no more than 40,000 FFS Medicaid beneficiaries, to qualify for an exemption. This would avoid placing unfair burdens on smaller states with fewer resources and would be less likely to carve out substantial groups of Medicaid beneficiaries.

Finally, if HHS retains the exception process for creating these APIs, the language and detail around a state's alternative plan for keeping FFS beneficiaries, providers, and payers informed of prior authorization decisions must be strengthened. The alternative described at proposed § 431.61(c)(2)(ii) must not only ensure that enrolled FFS providers have "efficient electronic access to the same information," but should require that their electronic access is comparable in detail, quality, and timeliness to the access afforded providers using the state's API system.[29]

Clarifying which FMAP applies to computer system upgrades

Funding is probably the major impediment to fully implementing these new electronic prior authorization systems, and also the principle reason for creating an exemption process in the regulations. The proposed regulation refers to a ninety percent federal match for developing new electronic claims processing and information retrieval systems and a seventy-five percent enhanced federal match for operating those system.[30] But the preamble language hedges on whether the enhanced federal match applies.

We urge HHS to clarify in the final rule or additional guidance that all or likely all of the required state investment to develop these APIs would qualify for enhanced federal match to establish

[29] 87 Fed. Reg. 76262.
[30] 87 Fed. Reg. 76264, referencing 42 U.S.C. 42 U.S.C. § 1396b(a)(3)(A)(i), which authorizes a 90% federal match for the design, development, or installation of mechanized claims processing and information retrieval systems; and 42 U.S.C. 42 U.S.C. § 1396b, allowing a 75% federal match for state expenditures to operate Medicaid mechanized claims processing and information retrieval systems.

and operate API systems. This would help ease state concerns about finding the resources to implement these systems that promise to reduce overall administrative burden and facilitate access to needed care for beneficiaries.

Ensure the payer-to-payer API includes all relevant payers

Proposed § 431.61(b)(2)(ii) requires states to share a beneficiary's opt-in preference with all Medicaid managed care plans in the state that provide coverage to that individual. We interpret this to include Medicaid MCOs, Prepaid Inpatient Health Plans (PIHPs), Prepaid Ambulatory Health Plans (PAHPs), Health Insurance Oversight systems (HIOs), Primary Care Case Management (PCCMs), and PCCM entities, but the regulatory language is not entirely clear. We recommend that the regulation clarify the scope of entities that must be notified of the enrollee's opt in preferences (and so included in the state's payer-to-payer API system).

We also recommend that HHS consider sharing the opt-in preference with Medicare managed care plans in the payer-to-payer API for dually eligible enrollees, rather than limiting the API to only Medicaid FFS and Medicaid managed care payers. This would facilitate care coordination across relevant payers for people who are dually eligible. The preamble notes that the standards in this regulation would apply to integrated plans for people dually eligible, but the Medicaid payer-to-payer API may also want to include such plans in that communication network, so long as enrollees opt in.[31]

§ 431.80 Prior authorization requirements

Improving the flow of information regarding prior authorizations between payers and between providers and payers may be the most consequential and beneficial development in this proposed rule. Providers are often in a better position to understand the administrative process for prior authorization – due to more frequent interactions – and the context for different kinds of denials. If a prior authorization request requires follow-up information, such as clinical test results or evidence of having tried and failed a different therapy, an individual's providers are often in the best position to quickly supply that information. Moreover, HHS should ensure that plans do not establish stricter clinical or administrative criteria for authorization than the state FFS program, as required by law.[32]

[31] 87 Fed. Reg. 76293.
[32] MCOs are defined as entities that "make[ ] the services it provides to Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other

We support the creation of standards-based provider and payer-to-payer Prior Authorization Requirements, Documentation, and Decision (PARDD) API for states to share information and facilitate more informed care decisions. We agree that this API should include the covered services requiring prior authorization, the information requirements to obtain prior authorization, and ongoing information about the status of submitted requests and state authorization decisions. As noted with the beneficiary API above, knowing the specific reason for denial is a crucial component of this information exchange. As above in § 431.60, we recommend that HHS elaborate in the final regulation that a specific reason must be based on ascertainable standards that include sufficient supporting documentation to understand the basis for reaching that decision.

Clinical coverage criteria for determining medical necessity should be transparent and consistent with generally accepted standards of care. The recent HHS Office of Inspector General's examination of prior authorization denials in Medicare Advantage plans found that the use of incorrect or additional coverage criteria not authorized by Medicare rules occurred relatively commonly, constituting thirteen percent of all prior authorization denials.[33] To prevent such denials, or at least make them easier to remedy, both plans and states should be clear about what their clinical criteria are and how they are applied, and that documentation and evidence should be explicitly required by regulation to be included in the state APIs for providers and payer-to-payer exchange.

We also note that for youth covered by Early and Periodic Screening, Diagnostic, and Treatment (EPSDT), Medicaid law requires that states cover any medically necessary service that could be covered under the Medicaid state plan, using a standard for medical necessity appropriate for this age group.[34] The API should thus include access to the prior authorization

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Medicaid beneficiaries within the area served by the entity." 42 C.F.R. § 438.2 (defining MCOs). MCOs cannot define "what constitutes medically necessary" services in a manner "more restrictive than that used in the State Medicaid program, including quantitative and non-quantitative treatment limits," 42 C.F.R. § 438.210(a)(5)(i). *See also* 42 U.S.C. § 1396b(m)(1)(A)(i) (defining a Medicaid managed care organization as one making services available to enrollees to the same extent as other Medicaid beneficiaries).

[33] HHS OIG, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns about Beneficiary Access to Medically Necessary Care*, 9 (Apr. 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[34] 42 U.S.C. § 1396d(r)(5).

documentation requirements and criteria for all the services that these young beneficiaries may need, even if those services are not covered under the state plan for adults.

§ 438.210 Coverage and authorization of services

We strongly support HHS's proposal to shorten current Medicaid managed care standard authorization timelines, but recommend that the proposed standard be reduced from seven days to seventy-two hours. Tracking timelines using hours instead of days will preclude any confusion or ambiguity regarding calendar days or business days. Because the new API rule requires plans to clearly identify what services require prior authorization, what criteria govern approval, and what information is required from providers to obtain authorization, we expect that processing prior authorization requests should become much easier over time. Any administrative delay in providing needed medical care should be minimized, and we see no reason not to establish a higher expectation for timely decisions, particularly since the rule already includes a pathway for an extension if justified as in the enrollee's interest.

For similar reasons, we support a tighter timeline for expedited prior authorization requests. The proposed rule makes no change in the current seventy-two hour timeframe for expedited decisions. We think such urgent requests should never be held up by administrative red tape, and should be made within twenty-four hours of a request, or faster if necessary.

The proposed language to allow states to set a tighter timeline is unnecessary and possibly counterproductive. States can already establish shorter time frames for expedited authorization decisions through state law, state regulations, or through managed care contracts. In fact, by proposing in the federal regulation that a shorter time-frame must be "established under State law," this proposed rule could seriously hamstring a state government from establishing stricter standards.[35] If finalized as proposed, the federal regulation could be interpreted to require a state to pass a law to establish a shorter expedited time-frame, rather than simply doing so through state agency rule-making or through the managed care contracting process. In many states, divided legislatures and biannual legislative sessions might make passing such a law extremely difficult.

We strongly recommend that HHS establish a twenty-four hour federal time-frame for expedited decisions. If HHS decides to leave the current standard at seventy-two hours or faster dependent on the health needs of the enrollee, we strongly recommend that HHS

[35] 87 Fed. Reg. 76363.

amend the proposed changes to the expedited authorization timeline to clarify that states can set stricter timelines through law or other policy-making mechanism.

§ 438.210(f) Publicly reporting prior authorization metrics

As recent reports have made clear, the prior authorization apparatus has created enormous administrative hurdles that lead to unnecessary and unjustified coverage delays and denials. Media exposés have also demonstrated that these denials stem not only from arcane bureaucratic complexity, but rather from strategic decisions capitated managed care organizations make to systematically deny needed care to improve their bottom line.[36]

One way to rein in abuses and streamline bureaucratic processes is to increase transparency and oversight reporting about the frequency, validity, and outcomes of prior authorization denials. We support requiring plans to publicly report data on the use and outcomes of prior authorizations of care. Shining a light on the frequency of denials has been instrumental to identifying, preventing, or correcting such abuses.[37]

However, the proposed rule does not go nearly far enough to require the granularity of data that would be necessary to identify and isolate abuses of the prior authorization system by managed care companies. Reporting aggregated data about approved and denied authorizations will mask cases where denials are targeted to a less common but particularly expensive services, or even by targeting individuals or groups of individuals with particularly high service needs.[38] We recommend that HHS require plans would report on prior authorizations at the plan level for specific categories of services, rather than overall aggregate rates. This would permit states to more easily link prior authorization practices with utilization rates for specific services – an important oversight tool.

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[36] Armstrong, note 4, *supra*; Johnson, *note 5 supra*; J. David McSwane & Andrew Chavez, *Pain & Profit Part 2: As Patients Suffer, Companies Profit*, DALLAS MORNING NEWS (Jun. 3, 2018), https://interactives.dallasnews.com/2018/pain-and-profit/part2.html.

[37] After Dallas Morning News published a major exposé of rampant care denials by Superior Health, a Medicaid managed care plan in Texas covering children in foster care, the state required the plan to begin reporting its denials. J. David McSwane & Andrew Chavez, *Pain & Profit Part 6: 'Recipe for Disaster:' How a Company's Refusals to Cover Medical Costs is Hurting Sick Forster Kids in Texas*, DALLAS MORNING NEWS (Aug. 26, 2018), https://interactives.dallasnews.com/2018/pain-and-profit/part6.html.

[38] Armstrong, note 4 *supra*.

We also recommend that HHS add to its list of required reporting to include:

1. The total absolute number of prior authorization requests along with the absolute number of denials, extensions, and approvals, not just the percent that were approved or denied, for each category of services;
2. The total number and the percentage of appeals related to prior authorization denials; and
3. The average time between a prior authorization approval and the actual provision of the approved treatment or service.

The current list or required data refers only to percentages, but does not include the absolute numbers of prior authorization requests, which is necessary to understand the scope of this utilization management practice.

3. Ensure that notice and appeal rights meet Medicaid due process requirements

As discussed above, we support HHS's proposal to increase enrollee access to prior authorization information through electronic API systems. However, API systems should supplement, not supplant, Medicaid due process requirements.

One of the most important features of the Medicaid program is the right to due process. The Medicaid statute guarantees applicants and beneficiaries the opportunity for a hearing when a claim is not denied or not acted on with reasonable promptness.[39] In addition, the Supreme Court has long recognized that the Due Process Clause of the U.S. Constitution entitles individuals to prior notice as well as a hearing when an individual is in jeopardy of losing publicly-funded medical care.[40] The Supreme Court's decision in *Goldberg v. Kelly* places a number of requirements on the Medicaid termination process, including the right to timely notice from the agency stating the basis for the proposed termination.[41] "[A] recipient [must] have timely and adequate notice detailing the reasons for a proposed termination, and an effective opportunity to defend" against termination.[42]

One of the fundamental requirements of procedural due process is that notice must be reasonably calculated, under the circumstances, to inform interested parties of the pendency

[39] 42 U.S.C. § 1396a(a)(3).
[40] *Goldberg v. Kelly*, 397 U.S. 254 (1970); U.S. Const. amend. XIV, § 1.
[41] 397 U.S. at 269-71.
[42] *Id*. at 267–68.

of the action and afford them opportunity to present their objections. To this end, HHS has required that Medicaid notices be in writing and contain "a statement of action the State" intends to take, a "clear statement" of the specific reasons supporting the intended action, and the regulations supporting the decision.[43]

Significantly, in *Goldberg*, the Court based its decision on the fact that low income people receiving public assistance are particularly vulnerable to wrongful termination of services because the assistance "provides the means to obtain essential . . . medical care" and their circumstances may become "immediately desperate" if assistance is terminated.[44] Thus, the procedures that govern disputes over Medicaid must account for the beneficiaries' particular need for it. Recipients of other governmental benefits, in contrast, may not need as high a degree of protection.[45] Therefore, while notice and hearing rights with regard to health care services are important for everyone, the rights of Medicaid beneficiaries require special solicitude. As the Supreme Court said, unlike:

> the blacklisted government contractor, the discharged government employee, the taxpayer denied a tax exemption, or virtually anyone else whose governmental entitlements are ended. . . termination of aid pending resolution of a controversy over eligibility may deprive an eligible recipient of the very means by which to live while he waits.[46]

For low-income people, "erroneous termination would damage [a beneficiary] in a way not recompensable through retroactive payments."[47]

Given the importance of due process protections, we are concerned that some health plans, payers, and providers may limit enrollee access to prior authorization denials and other health information to online or electronic portals only. According to a 2021 report by the Kaiser Family Foundation, an estimated one in four Medicaid enrollees live in a household with limited or no

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[43] 42 C.F.R. §§ 431.206(b), 431.210(a)-(c). See also *Strouchler v. Shah*, 891 F. Supp. 2d 504 (S.D.N.Y. 2012); *Ortiz v. Eichler*, 616 F. Supp. 1046, 1062 (D. Del. 1985) ("Fundamental due process requires that a person be informed in advance of the issues to be addressed at a hearing, so that he or she can be prepared to present evidence and arguments that address those issues.").
[44] 397 U.S. at 264.
[45] *Id.* at 263.
[46] *Id.* at 265.
[47] *Mathews v. Eldridge*, 424 U.S. 319 (1976).

internet and computer access.[48] HHS should ensure that plans do not require or coerce enrollees to receive prior authorization and other health information only through electronic mechanisms.

§ 431.201 Definitions & § 431.220 When a hearing is required

We support HHS's revision of the definition of an "action" to clarify that it includes termination, suspension of, or reduction in benefits or services for which there is a current approved prior authorization. We also support HHS's clarification that prior authorization decisions are one of the situations in which a state must provide an opportunity for a fair hearing when a beneficiary believes the agency has taken an adverse action. Making this requirement explicit will ensure that beneficiaries have access to a hearing when the state has not acted on a request for prior authorization. We appreciate HHS noting in the preamble that the failure to act on a claim, which gives rise to notice and hearing rights, includes failure to act on a request for prior authorization.[49] We recommend that HHS revise the regulatory language to make this explicit.

§ 435.917 Notice of agency's decision concerning eligibility, benefits, or services

We support HHS' decision to revise the subheaders in this section and clarify that the notice requirements apply to current recipients of services to make it clearer that the requirements apply to decisions about services as well as eligibility.

§ 440.230 Sufficiency of amount, duration, and scope

We enthusiastically support the addition of language making it clear that states must provide notice and hearing rights for decisions about prior authorization. We also support HHS's decision to impose standard time limits on making a prior authorization determination and allowing for one extension only when needed by provider or beneficiary. The decision to require prior authorization data will provide important information and enable monitoring of an important indicator of whether beneficiaries are receiving services in a timely manner. We do however, question why these requirements are included in this section, which does not concern notice or hearing rights but instead governs the scope of services. We suggest that

[48] Bradley Carallo, Kaiser Family Found., *Housing Affordability, Adequacy, and Access to the Internet in Homes of Medicaid Enrollees*, Fig. 3 (Sept. 22, 2022), https://www.kff.org/medicaid/issue-brief/housing-affordability-adequacy-and-access-to-the-internet-in-homes-of-medicaid-enrollees/.
[49] 87 Fed. Reg. 76299, citing 42 C.F.R. § 431.220(a)(1).

this requirement might be more appropriate in § 435.917, which governs notice of an agency's decision on eligibility, benefits, or services.

Finally, we support HHS stating that the revisions to these four sections are clarifications and not intended to change existing law.[50]

Conclusion

We have included citations and direct links to research and other materials. We request that the full text of material cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If HHS is not planning to consider these citations part of the record as we have requested, we ask that you notify us and provide us an opportunity to submit copies of the studies into the record.

Thank you for the opportunity to comment on these important issues. Please feel free to contact me at (202) 289-7661 or turner@healthlaw.org if you have questions.

Yours truly,

Wayne Turner
Senior Attorney

[50] *See, e.g.,* 87 Fed. Reg. 76299.