June 15, 2026

Submitted via regulations.gov

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: RIN 0938–AV44
Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans (QHP) on the Federally-Facilitated Exchanges

Dear Dr. Oz:

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 with respect to prescription drugs in Medicaid, the Children's Health Insurance Program (CHIP), and Qualified Health Plans (QHPs) sold through the Affordable Care Act (ACA) Marketplaces (hereinafter "Prescription Drug Proposed Rule").[1]

We welcome HHS's efforts to apply processing standards and public reporting to prior authorization requests for prescription drugs. The Prescription Drug Proposed Rule represents an important step to increase transparency and accountability in prior authorization and to streamline the decision-making process. We urge HHS to continue to build and improve upon its earlier rulemaking on prior authorization for non-prescription drug services.

1. Prior authorization impedes access to medically necessary care.

We support HHS's effort to bring greater efficiency, transparency, and accountability to prior authorization with respect to prescription drugs and urge the Department to go even further to protect patients from the increasing use of prior authorization and other utilization management as a claims-mitigation strategy.[2]

According to a survey conducted by the American Medical Association (AMA), 95% of physicians reported that prior authorization caused delays in care and 79% said prior authorization can lead to patients abandoning treatment due to the burden.[3]

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[1] Ctrs. for Medicare & Medicaid Services (CMS), *Proposed Rule - Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges*, 91 Fed. Reg. 19890–20062 (Apr. 14, 2026), https://www.federalregister.gov/public-inspection/2026-07205/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-standards [hereinafter Proposed Rule].

[2] In these comments, we use the term "patient" and "enrollee" interchangeably, recognizing that HHS largely uses the term "patient" in the Prescription Drug 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] Am. Med. Ass'n, 2025 Prior Authorization Physician Survey (Dec. 2025), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf [hereinafter 2025 AMA Survey]; J.C.

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.[4] 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.[5] In 2023, a Congressional request prompted the HHS Office of the Inspector General to conduct a broader review of prior authorization delays in Medicaid. The report revealed that the largest 115 Medicaid MCOs denied more than 2 million of the 17 million prior authorization requests – plans had denial rates above 25 percent.[6] Other recent OIG and GAO reports have found evidence that Medicaid and Medicare Advantage plans have applied inappropriate clinical criteria in denying prior authorization requests, or should not have applied prior authorization at all.[7]

Corder, *Streamlining the Insurance Prior Authorization Debacle*, 115 MO. MED. 312 (2018), https://pmc.ncbi.nlm.nih.gov/articles/PMC6140260.

[4] Assoc. of Black Cardiologists, *Identifying How Prior Authorization Impacts Treatment of Underserved and Minority Patients* (Feb. 2019), https://policycommons.net/artifacts/1794009/identifying-how-prior-authorization-impacts-treatment-of-underserved-and-minority-patients/2525653/.

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

[6] U.S. Dep't of Health & Human Servs., Office of Inspector Gen., *High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care* (July 2023), OE-01-19-00350, https://oig.hhs.gov/documents/evaluation/3157/OEI-09-19-00350-Complete%20Report.pdf.

[7] U.S. Dep't of Health & Human Servs Off. Inspector Gen., *Keystone First Should Improve Its Procedures for Reviewing Service Requests that Require Prior Authorization* (Dec. 20, 2022), https://www.oversight.gov/sites/default/files/oig-reports/HHSOIG/32000201.pdf (finding that a Medicaid MCO in Pennsylvania added nonclinical conditions to requests for overnight private duty nursing services); U.S. Dep't of Health & Human Servs Off. Inspector Gen., *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns about Beneficiary Access to Medically Necessary Care* (Apr. 27, 2022), https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp (finding that nearly 1 in 5 prior authorization denials issued by Medicare Advantage plans should have been approved under

For some insurers, managed care organizations (MCOs), and other payors, creating barriers and denying care is an effective business model designed to cut costs and maximize revenue, where patients and providers get worn down amid seemingly endless reviews and documentation requests. One concern with the Prescription Drug Proposed Rule is that establishing requirements, including public reporting of prior authorization approvals and denials, may lead payors to increase use of other utilization management tools, such as step therapy, concurrent and retrospective review, and pill limits, all of which come with their own harm to patients.[8] HHS should evaluate these potential consequences and harms to consumers and, where necessary, take regulatory action to prevent inappropriate use of other utilization management mechanisms.

A second concern with the Prescription Drug Proposed Rule, which also applies to the 2024 CMS Interoperability and Prior Authorization Final Rule (hereinafter 2024 Interoperability Final Rule), is that they seem to treat prior authorization as an interaction exclusively between payors and providers.[9] Patients and caregivers are hardly passive participants in the prior authorization process, particularly for those dealing with serious medical conditions. They are very often the ones pushing prior authorization requests through the system as providers

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Medicare medical necessity criteria); U.S. Gov't. Accountability Off., *Medicaid: Managed Care Plans' Prior Authorization Decisions for Children Need Additional Oversight* (Apr. 30, 2024), https://www.gao.gov/products/gao-24-106532 (finding that MCOs applied prior authorization to some EPSDT services even when not required by the state).

[8] *See, e.g.*, Y. Park et al., *The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review*, 23 J. MGMT. CARE & SPECIALTY PHARMACY (2017), https://pubmed.ncbi.nlm.nih.gov/28737993/ (documenting worsening patient outcomes when step therapy was instituted for opioid use disorder treatment).

[9] U.S. Dept. of Health & Human Srvs., *Final 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*, 89 Fed. Reg. 8758–8988 (Feb. 8, 2024), https://www.govinfo.gov/content/pkg/FR-2024-02-08/pdf/2024-00895.pdf [hereinafter 2024 Interoperability Final Rule].

spend thirteen hours a week or more completing prior authorization paperwork.[10] As discussed below, we urge HHS to make every effort to loop in patients and caregivers in the regulatory framework and implementation of prior authorization interoperability requirements.

2. HHS should establish stronger reporting requirements regarding prior authorization data and metrics.

Public reporting of what drugs (and services) are subject to prior authorization, approval and denial rates, appeals, and denials overturned on appeal, are all crucial for ensuring that plans and other payors are meeting their obligations to enrollees. 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.[11]

The 2024 Interoperability Final Rule requires plans and other payors to publicly post important prior authorization metrics for services, effective March 31, 2026.[12] However, compliance has been sporadic. Moreover, in the absence of clearer guidance from HHS, payor reporting of prior authorization for non-prescription drug services has taken a multitude of forms and formats, making it difficult for consumers and advocates to access.

It is unclear which state Medicaid agency fee for service (FFS) programs have complied with the prior authorization reporting requirements under the 2024 Interoperability Final Rule, nor is it clear if any states have sought or been granted waivers.

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[10] *See* 2025 AMA Survey, *supra* note 3.

[11] 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.

[12] *See* 2024 Interoperability Final Rule, *supra* note 9.

Some insurers have publicly reported prior authorization metrics, required under the 2024 Interoperability Final Rule.[13] However, the manner and form in which they present prior authorization data vary widely. Some insurers post information where it requires significant searching and multiple clicks to access. Instead of providing easily accessible data on prior authorization denial rates, other insurers are hyping voluntary efforts to address growing consumer dissatisfaction with burdensome prior authorization processes.[14]

We urge HHS to require more standardized public reporting of prior authorization metrics for both prescription drugs and other services. 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 an important moment in which health care consumers have power in the face of a multibillion-dollar health insurance company. 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 and performance, 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.

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[13] *See, e.g.*, Humana, Human Prior Authorization Metrics, https://provider.humana.com/coverage-claims/prior-authorizations/prior-authorization-metrics (last visited June 6, 2026); United Healthcare, Prior authorization made clear: 98.9% of Medicaid plan medical claims do not require prior authorization, https://www.uhc.com/legal/cms-interoperability-prior-authorization/medicaid (last visited June 6, 2026).

[14] Brit Vanneman, Nat'l Health Law Prog., Voluntary Industry Prior Authorization Commitments: Empty Promises, Little Accountability (July 8, 2025), https://healthlaw.org/voluntary-industry-prior-authorization-commitments-empty-promises-little-accountability/.

The posting of prior authorization metrics is already achieving results that will ultimately benefit consumers, including enrollees and potential enrollees, as well as researchers and health advocates. For example, a newly launched website, https://www.authdenied.com/, provided detailed information and user-friendly search engines allowing consumers to access granular data on services subject to prior authorization, denial rates, with tools to compare plans.[15] Another group set up a prior authorization report card, focusing on Medicare Advantage plans.[16] Importantly, while these websites are helpful, consumers should not have to rely on websites created by private groups. In fact, federal regulations already require states to create a user-friendly website to present the information.[17] Instead, these websites should instead serve as a model for what HHS requires of states.

In addition, health economists and researchers continue to analyze prior authorization metrics, with alarming, but not surprising, findings. For example, Dr. Eric Bricker shared his analysis of prior authorization metrics, which found that three top insurance companies, UnitedHealthcare, Elevance, and Humana, all had nearly identical prior authorization denial rates of 12.6–12.8 denials per 100 enrollees.[18] As Dr. Bricker concludes, this similarity strongly suggests these insurers are establishing prior authorization targets, using denials as a claims mitigation strategy, and not basing prior authorization decisions on medical necessity according to generally accepted clinical standards and up-to-date criteria.[19]

Despite the March 31, 2026 deadline under the 2024 Interoperability Final Rule, our review shows that many insurers and other payors, including state Medicaid agencies, have still not publicly posted prior authorization metrics. We understand the implementation challenges,

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[15] Prior Authorization Denial Rates by Health Insurer and State, https://www.authdenied.com/ (last visited June 3, 2026).
[16] Harris Secure Connect, The First-Ever Payer Prior Authorization Report Card Is Public. Here's What It Shows (April 3, 2026), https://harrissecureconnect.com/2026-payer-prior-authorization-report-card/.
[17] 42 C.F.R. § 438.520
[18] *See* Erick Bricker, MD, https://www.linkedin.com/posts/ericbrickermd_priorauthorization-priorauth-healthcare-ugcPost-7449293087631183872-qm6_/?utm_source=share&utm_medium=member_android&rcm=ACoAAAAU0BwBZni8HUF7sfye57-vzuxRV-rRjXU.
[19] *Id.*

since multiple agencies within HHS are responsible for regulating plans and programs covered by the 2024 Interoperability Final Rule and the Prescription Drug Proposed Rule, including the Center for Medicaid & CHIP Services (CMCS) and the Center for Consumer Information and Insurance Oversight (CCIIO). However, we urge HHS to take greater steps to monitor and ensure compliance.

Lastly, as we raised in our comments to the 2022 Interoperability and Prior Authorization Proposed Rule, we urge HHS to require the granularity of data that would be necessary to identify and isolate abuses of the prior authorization system. Reporting aggregated data about approved and denied authorizations will mask cases where denials are targeted to a less common but particularly expensive services, including prescription drugs, or even by targeting individuals or groups of individuals with particularly high service needs.[20] We recommend that HHS require plans to report on prior authorizations at the plan level for specific categories of prescription drugs, rather than overall aggregate rates. This would permit states to more easily link prior authorization practices with utilization rates for specific drugs – an important oversight tool.

3. HHS should require plans to provide detailed notice of denial of prescription drug coverage at point of sale.

Prior authorization uniquely impacts Medicaid enrollees and other health care consumers when accessing prescription drugs. It is often at the point of sale, the pharmacy, when enrollees learn that their prescription has been denied, often due to prior authorization requirements. In *N.B. v. District of Columbia*, the U.S. District Court noted that, on any given day, pharmacies in the DC area deny nearly one half of all Medicaid prescription claims.[21] The low-income DC residents who rely on Medicaid can leave the pharmacy empty-handed, and often without knowing why their prescriptions were denied, or what to do next. As the court explained:

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[20] 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.

[21] N.B. by Peacock v. District of Columbia, 244 F. Supp. 3d 176, 185 (D.D.C. 2017). The National Health Law Program is co-counsel for the plaintiffs in this case.

> The beneficiary here is given no indication why the prescription is being denied at the point of sale. As such, he is totally unable to determine what the next best step is. Although he knows that he's not getting Medicaid coverage for his prescription, he has no indication, for example, whether the denial is attributable to a mistake or omission by the doctor, a determination that the drug is not covered by Medicaid, or a determination that the individual is not eligible for Medicaid coverage. Without that information, he effectively lacks the opportunity to which the Supreme Court said he was entitled. In short, he does not know whether to contact his physician, contact the DHCF, or research his procedural rights and invoke his right to a hearing. This simply cannot constitute adequate notice. Some initial written notice of the reason for the denial will reasonably apprise the plaintiff of the denial, provide him with information that will assist him in deciding whether to invoke his procedural rights, and allow him to prepare for a hearing should he choose to invoke those rights. Furthermore, on a more practical level, some initial notice of the reason for denial will likely allow inadvertent or erroneous denials to be resolved quickly and through informal means.[22]

For patients, knowing the reason for a prior authorization denial is paramount and constitutionally required.[23] Providing point of sale notice explaining the reason for a prior authorization denial, as well as next steps an enrollee may take, including filing a grievance or appeal, would provide the strongest level of consumer protection across all payor types. HHS should therefore clarify that payors, including plans and state Medicaid and CHIP FFS programs, must provide enrollees as well as providers with the reason for a prior authorization denial, consistent with existing Medicaid due process requirements.

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[22] *Id.* at 182. *See also* Wayne Turner, Nat'l Health Law Prog., *When Patients Leave the Pharmacy Empty-Handed*, NHeLP Blog (Dec. 3, 2019), https://healthlaw.org/when-patients-leave-the-pharmacy-empty-handed/.

[23] 244 F. Supp. 3d at 182. *See, e.g.*, Chianne D. v. Harris, 814 F. Supp. 3d 1261, 1368 (M.D. Fla. 2026) (finding notices constitutionally deficient because they failed to "unambiguously communicate the State's decision to terminate benefits, the reason for that decision, or to whom it applies…[N]either the [notices] nor any other written notice details the reasons for the State's decision as necessary to allow the effected individuals to assess the accuracy of the decision and decide whether to appeal").

4. The Medicaid notice and hearing provisions establish the gold standard for consumer protections.

One of the most important features of the Medicaid program is the right to prior notice and a fair hearing. The Medicaid statute guarantees applicants and beneficiaries the opportunity for a hearing when a claim is denied or not acted on with reasonable promptness.[24] In addition, the Supreme Court has long recognized that the due process clause of the U.S. Constitution entitles individuals to a prior and meaningful notice and a prior and impartial hearing when an individual is in jeopardy of losing publicly funded medical care.[25] 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.[26] "[A] recipient [must] have timely and adequate notice detailing the reasons for a proposed termination, and an effective opportunity to defend" against termination.[27]

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 of the action and afford them a meaningful opportunity to decide whether to challenge the action, and, if so, 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.[28]

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

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[24] 42 U.S.C. § 1396a(a)(3).
[25] Goldberg v. Kelly, 397 U.S. 254 (1970); U.S. Const. amend. XIV, § 1
[26] 397 U.S. at 269–71.
[27] *Id*. at 267–68.
[28] 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, 1063 (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.").

circumstances may become "immediately desperate" if assistance is terminated.[29] Therefore, while notice and hearing rights with regard to health care services are important for everyone, the rights of Medicaid beneficiaries require special solicitude.

For low-income people, "erroneous termination would damage [a beneficiary] in a way not recompensable through retroactive payments."[30] Given the importance of due process protections, we are concerned that some health plans, payors, 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 KFF, an estimated one in four Medicaid enrollees live in a household with limited or no internet and computer access.[31] HHS should ensure that plans do not require or coerce enrollees to receive prior authorization and other health information only through electronic mechanisms and that they notify the enrollee of the reason for the denial of coverage of prescription drugs, as well as the provider.

The Medicaid protections, including notice, explanation, and opportunity to challenge a denial or reduction in services, are indispensable for low-income enrollees who rely on Medicaid services. Its robust, comprehensive framework should serve as the foundation for consumer protections in other health programs, such as CHIP, QHPs, and Medicare Advantage plans.

5. **Prescription drugs administered in inpatient settings should be subject to the same standards as covered outpatient drugs in Medicaid.**

HHS proposes to apply the non-drug items and services prior authorization requirements of the 2024 Interoperability Final Rule to drugs that are provided as part of a bundled service and are therefore not considered "covered outpatient drugs" under the Medicaid Act. While the Medicaid Act imposes a 24-hour timeframe requirement for covered outpatient drugs subject to prior authorization, the Act also excludes drugs provided as part of, or incident to and in the same settings as, other services. Therefore, HHS concludes, it would be more appropriate to

[29] 397 U.S. at 264.
[30] Mathews v. Eldridge, 424 U.S. 319 (1976).
[31] Bradley Carallo, KFF, *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/.

apply the 7-days/24-hour timeframe to the excluded drugs. We generally disagree with HHS's assessment that all drugs covered as part of a bundled service should be subject to the same prior authorization timeframes as the non-drug services in that bundle and we urge the department to, at a minimum, align timeframes for some of these drugs with the Medicaid Act's statutory requirements.

To justify aligning prior authorization timeframes for drugs excluded from the covered outpatient drug definition with the 2024 Interoperability Final Rule requirements, HHS uses the example of drugs administered in an inpatient hospital setting as part of a hospitalization course of treatment. We acknowledge that in that situation it may be unworkable and unnecessary to impose separate timeframes for prior authorization for drugs and non-drug services. However, there are various instances of drugs not fitting the covered outpatient drug definition that call for a more nuanced approach. For instance, medication-assisted treatment (MAT) for opioid use disorders (OUD) is often provided through opioid treatment program (OTPs), particularly when it involves the use of methadone maintenance treatment, which can only be provided in OTPs pursuant to federal law. OTP treatment often also involves administering and prescribing other medications for OUD, such as buprenorphine.

Medicaid typically pays for MAT at OTPs through bundled payments that cover the cost of the medications and other services rendered to provide support for maintenance treatment, including dispensing, administering, and monitoring medication adherence, counseling, peer support, toxicology testing, among other interventions. An important distinction between OTP bundled services and inpatient services is that, whereas the use of medications in hospital inpatient settings is often incidental to the course of treatment, the drugs themselves are the centerpiece of the bundled treatment in OTP settings. Nonetheless, section 1927(k)(3) of the Social Security Act allows for the exclusion of methadone and buprenorphine as covered outpatient drugs when provided in OTPs because they are provided "as part of" OTP treatment.

Imposing prior authorization on MAT for OUD, regardless of the setting of care, significantly curtails access to these medications that have been proven effective in reducing the burden of OUD and preventing overdose. A 2020 report from the Government Accountability Office (GAO) concluded that prior authorization requirements can "prevent[] timely access to MAT" and that "these delays could be life threatening, because patients may return to drug use and

possibly overdose before receiving their medication."[32] Similarly, a 2018 SAMHSA reports that prior authorization restrictions may delay access to treatment, add to provider burden, and "[t]he end result is often that the patient does not receive any medication."[33]

To protect the health of individuals with OUD in states that still use prior authorization for MAT at OTPs, a sound policy approach would be to align the prior authorization review timeframes with the statutory requirements in section 1927(k)(3) so that Medicaid plans have to provide a response within 24 hours of a request. Allowing states and plans to take longer than that only serves to delay necessary treatment and put lives at risk at a time when the number of overdose deaths is finally decreasing thanks in part to increased access to medications for OUD. States also have various other ways to address the low risk associated with MAT initiation. By design, OTPs offer medication administration under direct supervision, which significantly reduces any potential risk of addiction and dependence. In addition, through OTP licensing policies, states already often restrict the types of patients that can access treatment in order to account for potential misuse of the medications. Rather than further restricting access in already restricted settings, federal policymakers should be moving to facilitate access to methadone and buprenorphine regardless of setting.

Services for several other chronic conditions are also often provided as part of bundled services or in the same settings as other services. For example, specialty medications for Crohn's disease, rheumatoid arthritis, and multiple sclerosis are often bundled with pharmacy support, injection training, and delivery coordination. Drugs for End-Stage Renal Disease (ESRD) (such as iron supplements, anemia medications like erythropoietin, and bone disease medications) are often combined with dialysis sessions. In many of these situations, the medications are not provided incident to the course of treatment; rather, they are considered an essential component, if not the principal part of treatment.

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[32] U.S. Gov't. Accountability Off., *Opioid Use Disorder – Barriers to Medicaid Beneficiaries' Access to Treatment Medications* (Jan. 2020), https://www.gao.gov/assets/gao-20-233.pdf.
[33] Substance Abuse and Mental Health Servs. Adm., *Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose* (Nov. 2018), https://www.rsat-tta.com/Files/Medicaid-Coverage-of-Medication-Assisted-Treatment.

Based on the need to limit the reach of prior authorization in the instances described above, we urge HHS to apply the statutory 24-hour timeframe to drugs that are not considered covered outpatient drugs because they are provided as part of bundled services or in the same settings as other services. To avoid a situation in which states and plans would be required to make case-by-case determinations as to whether the statutory or 2024 Interoperability Final Rule approach applies, we suggest aligning all drugs with the statutory 24-hour timeframe. In the alternative, HHS should adopt regulatory language applying the 2024 Interoperability Final Rule timeframe to drugs not considered covered outpatient drugs, but *only when* provision or administration of the drug is incidental, and not indispensable, to the rest of the course of treatment. In cases when the drug is considered indispensable to the treatment, the statutory, 24-hour timeframe should apply.

6. HHS should require plans to provide information about medical necessity criteria used for prior authorization determinations of prescription drugs.

HHS should ensure that prior authorization criteria are clinically-based and based on the generally accepted standard of care. Insurers and other payors 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**.** Transparency for the clinical criteria used for prior authorization determinations is key to ensure that enrollees receive medically appropriate care. Coverage determinations must be based on individualized assessment of medical necessity, not as a claims mitigation strategy.[34]

To that end, we believe HHS should require plans to make available specific information to enrollees regarding the medical necessity criteria they are using to determine whether to approve a prior authorization request. Plans that cover certain services on paper often circumvent such coverage by imposing strict medical necessity criteria that are incompatible with generally accepted standards of care and which effectively create barriers to accessing

[34] *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* Nat'l Health Law Prog. et al., Amicus Brief in Wit v. United Health Care, https://healthlaw.org/resource/wit-v-united-behavioral-health-care-u-s-court-of-appeals-ninth-circuit/.

services.[35] In addition to prior authorization, other utilization control mechanisms imposed by plans (such as step therapy and quantity limits) are often inconsistent with the standard of care and, in fact, only serve to delay access to services considered medically necessary.

Traditionally, the only recourse that enrollees have had against adverse coverage determinations based on the use of improper medical criteria has been to appeal these decisions. However, appeals are not only time-consuming, complicated, and expensive for enrollees; they may also be ineffective to the extent that enrollees struggle to access the criteria employed by the insurer. Lack of transparency around medical necessity criteria used for prior authorization and other utilization management practices persist despite congressional and state action to require plans to base decisions on evidence-based and accepted standards of care.[36]

As such, we believe HHS should incorporate explicit requirements for plans to make available to enrollees the specific criteria used to make coverage decisions. We urge HHS to adopt a policy that would make the information available for all enrollees that request it after enrollment. In the alternative, HHS should require plans to incorporate in all adverse determination notices a statement explaining that the enrollee has the right to access and review the medical necessity criteria.

7. Medicaid FFS and MCOs should be subject to the same prior authorization standards.

NHeLP strongly supports HHS's proposal to eliminate the exemption for state Medicaid and CHIP fee-for-service (FFS) programs with relatively small FFS populations from the Prior Authorization API requirements and replace it with a limited implementation extension process (until the compliance date for the HIPAA Administrative Simplification requirements proposed in this rule).[37]

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[35] *Id.* at 8–10.
[36] *See, e.g.*, Am. Med. Ass'n, Fixing Prior Auth: Clear Up What's Required and When (Apr. 24, 2025), https://www.ama-assn.org/practice-management/prior-authorization/fixing-prior-auth-clear-what-s-required-and-when.
[37] Proposed Rule at 19893.

In comments to the 2022 Interoperability and Prior Authorization Proposed Rule, NHeLP expressed concern that the exemption would create a two-tiered Medicaid system where beneficiaries enrolled in exempt FFS programs would not receive the benefits of a streamlined prior authorization process available to managed care beneficiaries. Individuals remaining in Medicaid FFS tend to be those with complex needs or living in areas with low managed care participation, including people with disabilities, children with special needs, medically frail adults, LTSS users, and individuals in specific rural areas where managed care plans may not operate.[38]

State Medicaid agencies and MCOs have the flexibility to determine the medications and services that require prior authorization and prior authorization requirements can vary significantly between FFS and MCOs. [39] For example, among programs covering medications for OUD, a higher percentage of FFS programs (64%) than MCOs (42%) required prior authorization for buprenorphine, while a slightly higher percentage of MCOs (35%) than FFS programs 33%) required prior authorization for methadone. Beneficiaries may therefore encounter different prior authorization requirements depending on whether a service is delivered through managed care or FFS.[40]

Eliminating the exemption in favor of extension is particularly important because many Medicaid beneficiaries frequently receive services through multiple delivery systems rather than exclusively through either managed care or FFS. According to KFF, significant populations of Medicaid enrollees, including children, older adults, people with disabilities, and adults in the ACA expansion population, receive services through both managed care and FFS

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[38] Nat'l Health Law Prog., Comments on CMS-0057-P, Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes (Mar. 13, 2023). https://healthlaw.org/wp-content/uploads/2023/03/Prior-Authorization-NPRM-3.12.2023.pdf.
[39] MACPAC, *Prior Authorization in Medicaid* (Aug. 2024) https://www.macpac.gov/wp-content/uploads/2024/08/Prior-Authorization-in-Medicaid.pdf.
[40] Abraham J. Andrews, Christopher M. Harris, Sarah J. Westlake, & Colleen M. Grogan, Coverage and Prior Authorization Policies for Medications for Opioid Use Disorder in Medicaid Managed Care, 3 JAMA HEALTH F. e224001 (Nov. 4 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2798039.

arrangements.[41] Similarly, a majority of dual-eligible beneficiaries navigate multiple Medicaid delivery systems, and a significant number of beneficiaries continue to receive at least some Medicaid services through FFS.[42] Many states also continue to administer prescription drug benefits through FFS carve-outs, even for beneficiaries otherwise enrolled in managed care, while long-term services and supports remain disproportionately financed through FFS arrangements.[43] A beneficiary's access to electronic prior authorization, Patient Access APIs, Provider Access APIs, and other interoperability tools should not depend on whether a particular Medicaid benefit is administered through MCO or FFS.

These overlapping delivery systems mean that beneficiaries often encounter different administrative requirements depending on the service they are seeking, even when they remain enrolled in the same Medicaid program.[44] Exempting certain FFS populations from interoperability and prior authorization requirements would therefore perpetuate fragmentation, requiring beneficiaries, providers, and caregivers to navigate multiple prior authorization processes and information systems.

We appreciate HHS's recognition that maintaining an exemption for certain FFS populations would undermine the goal of creating a more consistent, interoperable prior authorization system across Medicaid programs. Requiring compliance by all state Medicaid and CHIP FFS programs will help ensure that beneficiaries have access to the same interoperability tools,

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[41] KFF, *10 Things to Know About Medicaid Managed Care* (reporting percentages of beneficiaries who receive services through both managed care and FFS arrangements). (Mar. 23, 2026) https://www.kff.org/medicaid/10-things-to-know-about-medicaid-managed-care/.
[42] KFF, The Landscape of Medicare and Medicaid Coverage Arrangements for Dual-Eligible Individuals Across States (Oct. 24, 2024) https://www.kff.org/medicare/the-landscape-of-medicare-and-medicaid-coverage-arrangements-for-dual-eligible-individuals-across-states/.
[43] KFF, 5 Key Facts About Medicaid Prescription Drugs (Mar. 13, 2026) https://www.kff.org/medicaid/5-key-facts-about-medicaid-prescription-drugs/. Center for Health Care Strategies, *What New Long-Term Services and Supports Data Show About Rebalancing – And How States Can Respond* (Jan. 22, 2026) https://www.chcs.org/what-new-long-term-services-and-supports-data-show-about-rebalancing-and-how-states-can-respond/.
[44] Stephen Bentfield et al., *CMS Seeks to Expand Interoperability Requirements to Drug Pre-Authorization (FAQ)*, Crowell & Moring LLP (Apr. 29, 2026), https://www.crowell.com/en/insights/client-alerts/cms-seeks-to-expand-interoperability-requirements-to-drug-pre-authorization-faq.

electronic prior authorization processes, and transparency protections regardless of whether a particular service is delivered through managed care or FFS. Consistent prior authorization and interoperability requirements across delivery systems will reduce administrative complexity, improve care coordination, and better advance the goals of the proposed rule.

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 an opportunity to submit copies of the studies into the record.

Thank you for the opportunity to comment on these important issues. If you have any questions, please contact Wayne Turner (turner@healthlaw.org) or Héctor Hernández-Delgado (hernandez-delgado@healthlaw.org).

Yours truly,

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