



March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Re: 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 ([CMS-0057-P](#))

Submitted electronically via regulations.gov.

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the proposed rule, "Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P)." NAMI, the National Alliance on Mental Illness, is the nation's largest grassroots mental health organization, providing education, support, public awareness, and advocacy in communities around the country. We are dedicated to building better lives for people affected by mental illness, and we have a unique perspective on how interoperability and utilization management practices like prior authorization affect our community and the treatments they need.

NAMI supports changes within this proposed rule that streamline, standardize, and clarify the prior authorization process. At the same time, we caution CMS to do everything within the agency's power to protect patient health data. We offer the following detailed comments and recommendations.

Background on the Need to Improve Prior Authorization

NAMI appreciates that the proposed rule intends to improve the prior authorization process with requirements for Medicare Advantage (MA) organizations, state Medicaid and CHIP Fee-for-Service (FFS) programs, Medicaid managed care plans and Children's Health Insurance Program (CHIP) managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges (FFE) (collectively referred to as "impacted payers"). Prior authorization is a utilization management process used by some health insurance companies to determine if they will cover a prescribed procedure, service, or medication. The process for obtaining prior authorization varies by insurer but involves submission of administrative and clinical information by the treating physician, and sometimes the patient. Prior authorization can be required at many phases of a patients' journey - when patients switch providers, after they have been treated for a certain number of visits, when their medication type or dosage prescribed is changed, or when they are prescribed a drug, procedure or service.

Prior authorization is often used to contain costs and service utilization and can be detrimental to mental health care access. Specifically, prior authorization policies have been associated with increased medication discontinuation, reductions in mental health visits, and increases in emergency room visits.ⁱ There is also evidence that utilization management decisions are not made consistent with clinical best practices. For example, a recent class action suit, *Wit v. United Behavioral Health (UBH)*, found that UBH created flawed medical necessity criteria for determining whether to cover mental health and addiction treatment that were based on its own financial interests rather than accepted clinical standards. Furthermore, a study by the GAO found that use of prior authorization is less likely to be granted for mental health hospital stays compared with medical and surgical hospital stays.ⁱⁱ Patients have the right to appeal denials, but those rights come with an additional burden and delay at a time when patients and their caregivers may be overwhelmed with complex and intensive care. This suggests a drain on time and resources, incentivizing away from optimal levels of care, rather than an actual dispute of necessary care.ⁱⁱⁱ

The effect on patients can be profound. Inefficient processes can delay decisions and consequently access to care, increasing health risks and poor outcomes. Improper denials may increase patient out-of-pocket costs or cause patients to abandon care. The process itself may have a chilling effect on individuals seeking out care and providers recommending it. The impact is also significant for providers as increased administrative burdens can drive mental health providers out of insurance networks, creating greater issues in affordability. Moreover, such requirements are a way for health insurance plans to supplant the role of the mental health care provider, circumvent mental health parity laws, and create unnecessary delays and added costs for patients. Said one witness during a November 2022 Senate Committee on Health, Education, Labor and Pensions (HELP) hearing on youth mental health, “[Prior authorization] is mind-numbing. It will take weeks sometimes getting prior authorization for community-based mental health services.”^{iv} Given the ongoing demand for mental health care in the U.S. – and the corresponding limited availability of mental health providers – NAMI specifically welcomes CMS’s attention to this issue and proposals to improve it.

CMS Should Finalize Proposals to Improve the Prior Authorization Processes

NAMI shares CMS’s goal of removing inappropriate barriers to care by streamlining prior authorization and other utilization management processes. While some utilization management protocols may be grounded in sound clinical decision making, such as prior authorization to limit drug-to-drug interactions or to prevent overprescribing of potentially addictive medication, the development of such protocols is typically done without much or any patient input, and the rationale for such decisions is not typically made public. Therefore, we support oversight and transparency of prior authorization processes and offer the following comments:

Finalize Proposal to Automate and Streamline the Prior Authorization Process. CMS proposes to require impacted payers to automate the process for providers to determine whether a prior authorization is required, identify documentation requirements, and exchange prior authorization requests and decisions from their electronic health records or practice management systems. CMS further proposes to require that information about prior authorizations be available for as long as the authorization is active and at least 1 year after the last status change. We feel it is essential for patients to have this information and avoid unnecessary delays in accessing vital mental health care and encourage CMS to finalize the proposal.

Finalize Proposal to Establish Timelines for Responding to Prior Authorization. Beginning January 1, 2026, CMS proposes to require impacted payers to provide notice of prior authorization decisions as expeditiously as a patient's health condition requires, but no later than seven calendar days for standard requests, and no later than 72 hours for expedited requests unless a shorter minimum time frame is established under state law. NAMI encourages CMS to finalize this standard as we believe it will help people with mental health conditions more expeditiously access needed medical care.

Finalize Proposal to Provide a Clear Reason for Prior Authorization Denials. CMS proposes to require that impacted payers make information about prior authorization requests and decisions for items and services available to patients no later than one business day after the payer receives the prior authorization request or there is another type of status change for the prior authorization. In the case of a prior authorization denial, the payer must provide a specific reason for the denial. NAMI strongly supports the availability of prior authorization decision-making by payers, which will provide more transparency and predictability to patients and providers, as well as help them identify potential violations in mental health parity law. We also urge CMS to be as specific as possible about what information must be included in a notice of denial and that it must be specific, complete, actionable, and communicated to patients in plain language. The information about reconsiderations must also be accessible particularly to those with limited English or digital proficiency or access.

Finalize Proposal to Publicly Report on Prior Authorization Approvals, Denials, and Appeals. CMS proposes to require impacted payers to report metrics in the form of aggregated, de-identified data to CMS on an annual basis about how patients use the Patient Access API. NAMI strongly supports public reporting on prior authorization metrics, which will allow patient advocates much-needed transparency on the prior authorization process and potential parity violations. We ask that CMS require that this information be publicly available in accessible, plain language formats with enough specificity to be useful to patients in making health care decisions. For example, information about the total number of denials may not be sufficient to help patients make informed decisions. Additional information such as aggregated data about the reasons for denials and the types of services and procedures most often denied might be more useful metrics. Overall, the greater the level of transparency and specificity in these metrics, the more useful the data will be to patients and advocates.

In addition to the proposed changes above, NAMI additionally recommends:

- 1) CMS should consider future rules that apply these prior authorization requirements to prescription drugs. Medications are often a critical form of treatment for people with mental health conditions and are often subject to prior authorization requirements. We do not believe there should not be inferior standards for access to prescription drugs and encourage CMS to expand this proposal to include prescription drugs.
- 2) CMS should ensure the Patient Access API allows for caregivers and dependents to have access where patients have provided consent, consistent with HIPAA.
- 3) CMS should also broadly ensure that individuals who do not have access to software or apps are not disadvantaged because they do *not* use an API. If any important notice is provided or response required via an app accessing a Patient API, CMS should require states and QHP issuers to make available to individuals upon request written methods of notice. Written notices may be needed for individuals who prefer to access health information on paper, or because

individuals may have a lost or damaged phone or may not have permanent access to a mobile device and/or high-speed internet.

- 4) CMS should require that prior authorizations be valid for the duration of treatment and/or set reasonable limits on the possible frequency of prior authorization requirements. Individuals with stable diagnoses and long-term treatment needs should not have to renew prior authorization on (for example) a monthly basis.
- 5) CMS should expand these prior authorization requirements to all forms of health coverage. We note that the proposal does not apply to timeframes for prior authorization processes for QHPs on the Federally Facilitated Exchange, which are required to provide notification of a plan's benefit determination within 15 days for standard authorization decisions and within 72 hours for expedited requests. We strongly encourage CMS to standardize this process across all forms of coverage, including ERISA health plans and Medicare, which are not included in this proposed rule.
- 6) CMS should consider future rules that apply these standards to other forms of utilization management. While we believe this proposed rule represents an important step forward, it is important to frame this initiative in the broader context of the challenges patients face from utilization management. Prior authorization is but one method of utilization management, and increasing use of electronic prior authorization is only one needed element of improving prior authorization for patients. For example, it is our hope that the infrastructure built to support electronic prior authorization will eventually also allow for the flow of information about step therapy so that if a patient changes providers or payers they will not have to repeat a step therapy protocol once stabilized on a treatment.

NAMI's Privacy Concerns with Application Programming Interface (API), Payer-to-Payer Data Exchange

CMS proposes to make information about prior authorizations more readily available to patients, providers, and among payers. At face value, NAMI strongly supports this proposal. Increased use of electronic health records, combined with interoperability initiatives, can improve the quality and efficiency of care for all patients and facilitate continuity of care, giving individuals with chronic conditions like mental illness the ability to drive their care plan to best achieve their health care goals. APIs, in particular, will give patients with mental health conditions and their providers more access to information and will reduce burdens on consumers and providers alike. Most importantly, patients will ultimately receive better coordinated care, which will be especially valuable to patients with multiple underlying health conditions.

While NAMI commends CMS on its efforts toward making information more readily accessible and usable for patients and providers, we are concerned about overall patient privacy, and in particular, reliance on tools like APIs that manage sensitive health data but are not strictly classified as health care providers and thus not covered by HIPAA. While payers are subject to HIPAA privacy protections, once information is in the hands of a third-party application developer, it may not have the same federal legal protections. As CMS notes, "We do not have the authority to regulate health apps that individuals may wish to use, or what those apps do with PHI." We fear circumstances in which patients will consent to information sharing either without fully understanding the lack of privacy protections, or doing so because they have little other option to view information on their prior authorization requests.

As more patient data is accessible electronically via health apps, risks increase of security breaches, compromised confidentiality of health information, and inappropriate use of patient data for marketing. There are many recent examples of health apps failing to notify consumers and others of their unauthorized disclosures of consumers' personal health information, at times contrary to their privacy

promises. Just recently, online mental health counseling service BetterHelp was banned from sharing consumer health data for advertising purposes and fined \$7.8 million under a proposed Federal Trade Commission order after BetterHelp revealed sensitive consumer data to third parties like Facebook and Snapchat, after pledging to keep such information private.^v Consequently, we urge greater privacy protections and transparency about the use of data by third-party applications. It is critical that patients trust and know how their data will be used by anyone that will have access to it. CMS should require standards and transparency about data use by third-party apps and create plain language resources for patients and providers to understand their privacy rights. CMS should consider if and how the transfer of sensitive parts of records through the API can be suppressed. Without such a mechanism, using an API might be an “all or nothing” choice that some consumers will reject or be harmed by, particularly those who feel one of their diagnoses or treatments is private. Enabling such suppression will not impact the large majority of consumers who will not suppress any parts of their records in an API, and it will enable full participation for some individuals.

NAMI is also concerned that in making this information available only through APIs, patients are at the mercy of app design and usage – whether they are accessible to individuals with disabilities, available in a multitude of languages to ensure that individuals with limited English proficiency can understand the information provided, and the overall availability of apps at an appropriate literacy level and in plain language. Use of apps may be hardest for individuals with the most serious of health conditions, for whom information on prior authorizations may be of critical importance. While CMS proposes to require affected payers to provide educational materials to consumers about the new API functionality, we note that payers will have little incentive to adequately educate beneficiaries on API tools and encourage their use. We recommend CMS ensure that all communications to patients, whether in the information available through an API or the educational materials designed to help patients understand how to use an API, be accessible to all, including those with limited English proficiency and those with disabilities. The Patient Access API is subject to nondiscrimination requirements under Section 1557 of the Affordable Care Act, and CMS should remind developers of this fact during implementation.

Conclusion

NAMI is grateful for the many proposals within this rule, which we believe will help create much-needed automated processes and documentation clarity with respect to the prior authorization process. As CMS moves forward in developing interoperability and electronic prior authorization standards, we urge you to continuously engage with stakeholders, including patients with chronic conditions like mental illness and disabilities, so that the new systems that are created meet patient needs. We support efforts to enhance patient and provider access to health information that protect privacy, cover all forms of mental health services, across all relevant payers. Thank you for the opportunity to comment. For questions or further information, please contact Jennifer Snow, National Director of Government Relations and Policy at jsnow@nami.org.

Sincerely,



Hannah Wesolowski
Chief Advocacy Officer
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ⁱ https://ps.psychiatryonline.org/doi/full/10.1176/ps.62.2.pss6202_0186

ⁱⁱ <https://www.gao.gov/assets/gao-22-104597.pdf>

ⁱⁱⁱ [https://ajemjournal-test.com..marlin-prod.literatumonline.com/article/S0735-6757\(16\)00107-8/fulltext](https://ajemjournal-test.com..marlin-prod.literatumonline.com/article/S0735-6757(16)00107-8/fulltext)

^{iv} <https://www.fiercehealthcare.com/providers/mental-health-providers-decry-mind-numbing-prior-authorization-burdens-senate-debates>

^v <https://abcnews.go.com/Health/wireStory/betterhelp-shared-users-sensitive-health-data-ftc-97596138>