January 4, 2021

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: CMS-9123-P Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

Dear Administrator Verma:

NAMI, the National Alliance on Mental Illness, appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule refining prior authorization processes in Medicaid and Children's Health Insurance Program (CHIP), and for issuers of qualified health plans on the Federally-facilitated exchanges (the Proposed Rule).

NAMI is the nation's largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness. We appreciate CMS' efforts to reduce longstanding inefficiencies in the health care system that impact patient access and outcomes, including those associated with limited data sharing, and overly burdensome and opaque prior authorization processes. We believe that the most effective way to manage health care costs is through allowing clinical considerations and medical expertise to drive treatment decisions.

Our comments focus on these important areas:

- Reducing provider burden and patient delays associated with prior authorization (PA) processes
- Exclusion of Prescription Drugs and Covered Outpatient Drugs
- Medicare Advantage
- Balancing Access to Health Information with Patient Privacy

The following is our specific response to the details of the proposed rule.

Reducing provider burden and patient delays associated with prior authorization (PA) processes.

NAMI applauds CMS for its proposals to remove inappropriate barriers to care by streamlining prior authorization processes and increasing transparency on Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges (collectively, impacted payer(s)) use of this utilization management tool. We agree with CMS' assessment that prior authorization can be an overly-burdensome process leading

to dangerous delays in treatment, diverting clinician time away from patient care, and general inefficiency. For individuals with chronic diseases and disabilities like mental illness, onerous prior authorization processes can create significant barriers to timely, appropriate mental health care and negatively impact patient health outcomes. Sadly, we know what happens when people with a mental illness don't get treatment; they can end up in hospital emergency rooms, in jail, or on the streets with worse long-term outcomes and at greater cost to the state and the federal government.

NAMI views CMS' Proposed Rule as an important initial step toward increased transparency and reduced provider burden and encourages CMS to further refine its proposals prior to finalization. The recommendations below are intended to streamline the prior authorization process and ensure providers and patients quickly get the information and approvals they need to access appropriate care. Specifically, NAMI:

- Supports CMS' proposal to require that impacted payers build and maintain a Fast Healthcare Interoperability Resources (FHIR)-enabled document-requirement lookup-system (DRLS) application programming interface (API) capable of integration with provider electronic health-record (EHR) systems. This requirement would enable providers to electronically locate prior-authorization requirements for each impacted payer and improve efficiencies across the health care system. NAMI strongly agrees that impacted payers must be transparent about all coverage restrictions and the supporting clinical documentation needed to meet utilization-management requirements.

- Applauds CMS' proposal to require that impacted payers develop and maintain an interoperable electronic Prior Authorization Support API so that payers can send prior authorization requests to providers and receive responses electronically.

- Urges CMS to refine its proposal to require that impacted payers include a specific reason for any prior authorization request denial. NAMI is concerned that the term "specific reason" is subject to varying interpretation. CMS provided examples of payer explanations that would meet the requirement of a "specific reason" for denial, including that documentation was not provided, the patient had exceeded allowable limits, or that the item or service are not determined to be medically necessary. We urge CMS to refine its regulatory language to provide clarity and ensure that the information providers receive from impacted payers is sufficiently granular to inform next steps, including identification of any covered alternative treatments as well as appeal options.

- Encourages CMS to shorten the time period within which impacted payers must send their prior authorization decisions to providers. Prompt access to care is particularly critical for individuals with chronic conditions like mental illness.

- The 72-hour period for urgent requests and seven days for standard requests does not go far enough to facilitate prompt access to care. NAMI would prefer, for example, creating three (rather than two) time sensitivity categories and permitting 24 hours for urgent requests, three calendar days for time-sensitive requests, and seven calendar days for standard requests.

- Urges CMS to require that impacted payers ensure that an approved prior authorization remains valid for a sufficient time period to allow patient access to care. This is particularly important for patients with mental illness, such as those who may be waiting for treatment in an inpatient setting.

Exclusion of Prescription Drugs and Covered Outpatient Drugs

CMS specifically determined to exclude prescription drugs and/or covered outpatient drugs from the provisions of the Proposed Rule. NAMI has significant concerns that this decision will substantially reduce the utility of the Proposed Rule in reducing patient and provider burden and care delays associated with impacted payer use of prior authorization. We urge CMS to utilize the time period available between promulgation of this proposal and the anticipated 2023 implementation date to assess and address any complicating factors that would substantiate the inclusion of prescription drugs.

Individuals with chronic diseases and disabilities like mental illness, and their treating providers, often find that the greatest level of burden and uncertainty is associated with payer coverage for prescribed and administered medications. Incorporation of accurate formulary data and prior authorization and step therapy requirements into electronic health records (EHRs) is absolutely critical to ensure that providers have the information they need at the point of care. When prescription claims are rejected at the pharmacy due to unmet prior authorization requirements, treatments are delayed or completely abandoned. This can be particularly harmful for people with mental illness because a medication that works well for one person with schizophrenia often doesn't work well for another. These individual responses to mental health medications, along with differing symptoms and frequent, co-occurring physical health conditions, emphasize the need for carefully considered medication decisions. Provider access to after-the-fact data on claims submission is only helpful if it is available in real-time and contains the types of information CMS proposes to require for all other items and services. We strongly urge CMS to apply the prior authorization process requirements in the Proposed Rule to prescription drugs and covered outpatient drugs.

Medicare Advantage

NAMI urges CMS to include Medicare Advantage plans within its set of impacted payers. CMS has finalized policies through its recent Interoperability and Patient Access final rule[1] requiring Medicare Advantage Organizations to build and maintain APIs that provide the foundation for the requirements of this Proposed Rule.

As CMS noted, the Proposed Rule, "if finalized, would create misalignments between Medicaid and Medicare that could affect dually eligible individuals enrolled in both a Medicaid managed care plan and an MA plan." Nearly one-third of dual-eligibles have been diagnosed with a serious mental illness, a rate nearly three times higher than that of non-dually eligible Medicare beneficiaries.[i] For these reasons, NAMI has significant concerns that the identified misalignments are most likely to affect the most vulnerable patients like those with mental illness, and believes this factor alone is a sufficient rationale for applying the policies in the Proposed Rule to Medicare Advantage organizations.

Balancing Access to Health Information with Patient Privacy

NAMI appreciates that CMS recognizes the patient privacy considerations impacted through increased sharing of health care data across multiple entities. CMS has previously noted that a clear, plain

language privacy policy is the primary way to inform patients about how their information will be protected and how it will be used once it is shared with a third-party.[3] We support CMS' proposal requiring impacted payers to request a privacy policy attestation when a third-party application (app) seeks access to patient health care data and agree the attestation should include whether:

- The app maintains a publicly available and accessible privacy policy that is written in plain language. NAMI urges CMS to require the policy be available in language that is short and understandable to the patient. This can be achieved by CMS engaging the patient community to develop template language.

- The third-party app developer has affirmatively shared its privacy policy with the patient prior to gaining authorization to access the health information. This would mean the patient has to take action indicating that he/she was provided and acknowledged receiving the privacy policy.

- The app's privacy policy includes, at a minimum:
    - How a patient's health information may be accessed, exchanged, used, shared, or sold at any time
    - Express consent from a patient before the patient's health information is accessed, exchanged, or used, including receiving express consent before a patient's health information is shared or sold and, ideally, the patient should be able to indicate consent level for each use
    - If an app will access any other information from a patient's device
    - How a patient can discontinue app access to their data and device
    - The policy and processes used for disposing of a patient's data once the patient has withdrawn consent

Increased use of electronic health records, combined with interoperability initiatives, can improve the quality and efficiency of care for all patients and facilitates continuity of care, giving individuals with chronic diseases and disabilities the ability to drive their care plan to best achieve their health care goals. These benefits, however, are not without risk to each individual's privacy with respect to their health status and care. NAMI appreciates that CMS seeks information that may support future rulemaking or other initiatives on whether patients and providers should have the ability to selectively control the sharing of data in an interoperable landscape. We strongly encourage further investigation into approaches that provide information and flexibility for patient decision making while protecting patient privacy and ensuring informed consent.

We believe that the balancing of the benefits and risks associated with increased sharing of health care data across entities warrants informed consent processes that give patients the opportunity to choose how their data can be used, who can use it, and when it can be accessed. NAMI supports health data sharing informed consent processes that:

- Provide sufficient clarity to enable the patient to fully understand what is being shared, who it is being shared with, how it is used, and how long the consent remains in effect
- Presented in a language and literacy level that is appropriate for the patient
- Enables the patient to decline to share data that is not essential to claims for specific services, without having to opt out of receiving care from the provider or coverage through the payer

- Provides a clearly defined and easy to implement option for the patient to change or revoke their consent over time

NAMI strongly encourages CMS to engage stakeholders, particularly the patient community, as it further refines the checks and balances necessary to facilitate efficient health care information exchange while respecting patient privacy interests.

Conclusion
Thank you for the opportunity to comment on the Proposed Rule. If you have any questions, please contact me at jsnow@nami.org.

Sincerely,

/s/

Jennifer Snow
Director of Public Policy
National Alliance on Mental Illness

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[i] Congressional Budget Office. "Dual-Eligible Beneficiaries of Medicare and Medicaid: Characteristics, Health Care Spending, and Evolving Policies." June 2013. Available at: https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/44308dualeligibles2.pdf. This report classified Medicare beneficiaries as having a mental illness if they had a diagnosis from the previous year of schizophrenia; major depressive, bipolar, and paranoid disorders; or other major psychiatric disorders.