March 13, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Proposed Rule and Request for Information; Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

Thank you for the opportunity to respond to the Advancing Interoperability and Improving Prior Authorization Proposed Rule. We greatly appreciate the Centers for Medicare and Medicaid Services' (CMS) ongoing efforts improve patient access to essential services and treatments.

The undersigned organizations represent millions of patients and consumers facing serious, acute and chronic health conditions across the country, including individuals who rely on Medicaid, the Children's Health Insurance Program (CHIP) and ACA marketplace coverage. Our organizations have a unique perspective on what patients need to prevent disease, cure illness and manage chronic health conditions. Our breadth enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion.

In March 2017, our organizations agreed upon three overarching principles[1] to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit (EHB) package.

Prior authorization is a time-consuming process that can burden providers, divert valuable resources away from direct care, and cause delays in patient access to needed services and treatment. Our organizations are pleased to see the administration's ongoing commitment to improving the accessibility, affordability, and adequacy of care for all patients and are confident the policies included in this proposed rule will advance these shared goals. We offer the following comments and recommendations addressing specific provisions in the proposed rule.

Application Program Interface (API)
Our organizations are generally supportive of CMS's effort to advance the use of APIs in Medicaid, CHIP, and qualified health plans (QHPs) on federally facilitated exchanges (FFEs), including the new provider, payer-to-payer, and PARRDD APIs. APIs will give patients with chronic illnesses 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. 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.

Prior authorization processes heavily impact health care access, particularly for individuals with complex health care needs, and are an important part of health records. Although prior authorization can play an important role in ensuring patients get appropriate care, studies show that prior authorization can limit access to expertly developed standard-of-care treatments.[2] One survey of physicians found that more than one-third reported that prior authorization led to a serious adverse event, including hospitalizations, disability or even death.[3] 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. We support the broad inclusion of prior authorization information in patient, provider, and payer-to-payer APIs. In particular, we support the required inclusion of prior authorization details, including information on the items and services to which prior authorization applies and the specific reason for denials.

In addition, CMS should include prescription drug information in APIs, and broadly include prescription drugs in the regulatory provisions (except for the changes to prior authorization timelines). Individuals

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[1] Consensus Health Reform Principles. Available at: https://www.lung.org/getmedia/0912cd7f-c2f9-4112-aaa6-f54d690d6e65/ppc-coalition-principles-final.pdf.

[2] "Vital Access: How Policymakers Can Streamline the Cancer Care Journey," Leukemia & Lymphoma Society, Jan. 2023. Accessed at https://www.lls.org/sites/default/files/2023-01/vital_access_2023.pdf

[3] 2021 AMA Prior Authorization Physician Survey. American Medical Association. Accessed at https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

with chronic illnesses depend upon prescription drugs as an integral part of their health care, and there should not be inferior standards for access to that part of their treatment.

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.

Furthermore, we urge CMS implement these new requirements all at once, rather than allowing a lengthy phased-in approach, with all information integrated into APIs available to patients at the start rather than in stages. We are concerned that a phased-in approach could be confusing to patients who may have access to an API for some providers and not others.

We have some limited comments on specific APIs as follows:

Patient Access API
We support the requirement for reporting on Patient API usage. We ask CMS to clarify how API access will be handled for family caregivers, HIPAA designated healthcare proxies, and children, including children in foster care. In addition, CMS should ensure the Patient Access API allows for caregivers and dependents to have access where patients have provided consent, consistent with HIPAA.

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 redundant written methods of notice. Written notices may be needed for individuals who prefer to access health information in paper rather than electronic form, 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.

Provider Access API
We support the requirement to provide information to individuals in simple language about APIs and their right to opt *out* of participation. If properly implemented, Provider Access APIs have potential to meaningfully improve care for individuals with chronic conditions who often depend on a team of medical providers. We believe most individuals would choose to participate and benefit from participation if they are adequately informed of their rights and the potential uses of an API.

Payer-to-payer API
We support the requirement to provide educational materials and information to Medicaid beneficiaries and QHP enrollees in simple language about APIs and their right to opt *into* participation. Patients do not transition between plans with great frequency, and health plans can ensure new enrollees sign opt in materials. The current cross-references in the regulation appear to not require an opt in for Medicaid managed care; CMS should require the opt in for Medicaid managed care as well.

Prior Authorization Requirements, Documentation, and Decision (PARDD) API:
Finally, we support the development of an API that could streamline and automate the prior authorization process. Individuals with chronic illnesses are often harmed by delays or failures in prior authorization processes that require providers to file paperwork in the days or sometimes weeks after

patient visits. If all information needed for prior authorization requests could be reviewed in real time, and in many cases possibly resolved in real time, it would allow providers and patients to consider next steps, treatment instructions, or other treatment options at the same visit. This would reduce burden and improve care.

Communication with Providers
We strongly support requirements across programs to communicate prior authorization statuses to providers, including a reason for denial. CMS should require specificity on the reason for denial. For example, if the prior authorization request was denied due to the lack of submission of key documentation, that should be specified. In particular, "medical necessity" denials cover a wide range of potential factors, and states, plans, and QHP insurers should need to provide a more granular response than "failure to establish medical necessity." We urge CMS to require states, plans and QHP issuers to clearly articulate the standard used to determine medical necessity.

Moreover, we believe CMS needs to include prescription drugs in the prior authorization requirements. While we recognize that the processes and standards of prior authorization for drugs differ from those for items and services, we urge CMS to include prescription drugs in future rulemaking on prior authorization. Prescription drugs are often a key component of care for individuals with chronic health conditions who are prescribed complex drug regimens which need to be managed to ensure they are best suited for the individual and to avoid drug interactions. We believe that excluding prescription drugs from the prior authorization requirements will result in a significant burden to providers and patients who will have to manage multiple systems in order to ensure that the patient has access to medically appropriate treatments.

We also urge CMS to create similar guardrails around prior authorization for medications. Many people with chronic health conditions take the same medications for decades, yet still face "prior" authorization to continue taking these medications. Enrollees and physicians consistently report yearly or "surprise" prior authorization requirements for medications that the enrollee is already taking. Enrollees often only discover a new prior authorization requirement when they contact the pharmacy for a refill, risking a gap in care. Such gaps in care can lead to an exacerbation of symptoms or avoidable emergency department visits. Provider and Patient Access APIs could help providers and patients be alerted to new prior authorization requirements before the patient has run out of medication. Further, a Payer-to-Payer API should require payers honor existing authorizations for medications.

Reporting Requirements
Our organizations strongly support the requirement for reporting on prior authorization metrics, including both the requirements around providers initiating prior authorizations electronically and the broad reporting required for plans and states. CMS should also require states, plans, and QHP insurers to report on the items and services for which prior authorization was approved or denied (in addition to overall rates of denials and approvals). Furthermore, CMS should require reporting data be disaggregated by factors including service type, provider type, diagnosis, race and ethnicity, and age. It is critical for data to identify prior authorization problems that repeatedly target certain subpopulations, such as treatments for people with specific illnesses. In addition, we strongly urge CMS require data provided in a standardized format and available publicly, allowing for comparisons across plans, states, insurers and coverage programs.

CMS should develop additional regulations that add managed care prior authorization reporting metrics to the External Quality Review Organization (EQRO) performance metrics set. Regardless of how CMS

includes (or excludes) prescription drugs from this regulation, CMS should require that prior authorization for prescription drugs be included in the reporting requirements. There is no compelling reason to exclude prescription drugs from reporting and including it would be of great value. Finally, we believe all of these requirements should apply to CHIP.

Prior Authorization Time Frames
We support the modernization of prior authorization timeliness and believe the efficiencies created by this automated process make that possible and necessary. We recommend that standard requests should be resolved in 72 hours and expedited requests in 24 hours. Individuals with chronic illness are frequently harmed by unnecessary delays in receiving needed treatments. We recommend that extensions should be limited to 168 hours (the equivalent of 7 days). CMS should also require that patients and providers receive a notice of extension when a state or plan takes an extension. Timelines for prior authorization for prescription drugs in Medicaid should not be addressed through the regulation, since it is addressed in statute at § 1927(d)(5), and nothing in the regulation should negate the statutory obligation to provide a 72-hour supply of medications for emergency situations.

CMS should require that prior authorizations be valid for the duration of treatment and/or set 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. This is a waste of resources for enrollees and providers, and sometimes leads to treatment gaps that are totally avoidable.

Finally, CMS should require that prior authorization criteria be publicly reported. Many patients with chronic illnesses are denied treatments based on unknown criteria that contradict the conclusions of the medical professional that actually provide their care. Proprietary criteria should not be allowed, or, at a minimum, the medical standards on which that the criteria are based (for example, an academy recommendation) must be publicly reported. Patients and providers should have some basis to know if prior authorization criteria are properly designed and applied.

Fair Hearings, Notice, and Due Process
We support the changes to notice and appeals regulations to confirm that due process applies to prior authorization processes. We urge CMS to broadly review how notice is provided through prior authorization processes. Patients should always receive the required notice when a service is denied, regardless of whether they use digital communication methods (such as APIs) and of where/how the denial takes place (such as a denial at a pharmacy). Any delays between a denial and notice reduces an individual's ability to understand and respond to an improper denial.

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data
Our organizations are pleased to see CMS is considering ways to effectively and efficiently incorporate social risk factor data into patient records and patient care. Doing so will allow providers and payers to consider ways in which factors such as housing instability and food insecurity influence patient health and health care utilization. We look forward to working with CMS on this issue moving forward.

Conclusion
Thank you for considering this input on the prior authorization proposed rule. Please contact Theresa Alban with the Cystic Fibrosis Foundation at talban@cff.org with any questions.

Sincerely,

Alpha-1 Foundation
American Cancer Society Cancer Action Network
American Kidney Fund
American Liver Foundation
American Lung Association
Asthma and Allergy Foundation of America
Cancer Support Community
Cancer*Care*
Chronic Disease Coalition
Cystic Fibrosis Foundation
Epilepsy Foundation
Hemophilia Federation of America
Lupus Foundation of America
Muscular Dystrophy Association
National Alliance on Mental Illness
National Kidney Foundation
National Multiple Sclerosis Society
National Patient Advocate Foundation
Susan G. Komen
The AIDS Institute
The ALS Association
The Leukemia & Lymphoma Society