March 13, 2023

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
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 (QHP) 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

Dear Administrator Brooks-LaSure:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule. Our comments focus on the sections of the proposed rule relating to improvements in prior authorization practices.

CPR is a coalition of more than 50 national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain their maximum level of health and independent function. CPR is comprised of organizations that represent patients – as well as the clinicians who serve them – who are often inappropriately denied access to rehabilitative care in a variety of settings.

CPR commends CMS's efforts to incorporate patient and provider comments into their proposal to improve interoperability and streamline the prior authorization process. CPR strongly agrees with CMS's statements in support of health equity measures to increase access to health information for individuals with disabilities and individuals with limited or low health literacy. CPR further applauds CMS for addressing key issues relating to the overuse and misuse of prior authorization, including requiring specific reasons for denial, shortening timeframes for decisions, and requiring transparency from payers such as publishing data with respect to denial

and appeal rates. This proposed rule would be an important step forward in the process of curtailing the misuse—and in some cases, abuse—of utilization management tools and strengthening transparency for rehabilitation patients enrolled in impacted plans, particularly Medicare Advantage (MA) plans.

Prior Authorization Misuse and Overuse

While prior authorization may be appropriate in some limited circumstances to ensure that patients are receiving medically necessary and clinically appropriate care, the overuse and misuse of such requirements has become increasingly routine, especially in MA plans. The overutilization of prior authorization has become one of the most impactful negative pressures on access to medically necessary care in the post-acute care and rehabilitation benefit across all payers, often preventing beneficiaries from receiving the treatment they need in order to regain and/or maintain their health and function following injury, illness, disability, or chronic condition.

We strongly support CMS's commitment to reining in the prior authorization practices health plans and programs employ through this proposed rule and the recent Medicare Advantage proposed rule (CMS-4201-P). This proposed rule is a lifeline to the thirty-one million people enrolled in MA (nearly 50% of the eligible Medicare population) and millions of others in Medicaid, CHIP, and QHPs who are subjected to endless barriers to care, delays, and unjust denials for rehabilitation treatment and services.

For instance, in analyses of MA plans' use of prior authorization, government and private organizations have found serious issues with how frequently MA plans are requiring and denying prior authorization requests. The Department of Health and Human Services Office of the Inspector General (OIG) released a report in 2018 that detailed "widespread and persistent problems related to denials of care and payment in Medicare Advantage plans."[1] A second OIG report in 2022 found persistent problems with MA plans issuing inappropriate denials of service and payment, including denials of prior authorization requests that met Medicare coverage rules.[2] A recent Kaiser Family Foundation (KFF) report found that in 2021, MA plans received over 35 million prior authorization requests.[3] More than 2 million of these requests were fully or partially denied and yet, when appealed, the vast majority (more than 80%) of appeals were fully or partially overturned. Unfortunately, only 11% of initial denials were appealed, demonstrating not only the burden of appealing prior authorization denials but also indicating that many beneficiaries are likely seeing their care being inappropriately denied.

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[1] U.S. Department of Health and Human Services, Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denial; Report (OEI-09-16-00410) (Sept. 2018).

[2] U.S. Department of Health and Human Services, Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care; Report (OEI-09-18-00260) (Apr. 2022).

[3] Biniek, Jeannie Fuglesten, and Sroczynski, Nolan, Over 35 Million Prior Authorization Requests were Submitted to Medicare Advantage Plans in 2021. Kaiser Family Foundation (KFF) (Feb. 2023). https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021.

According to a 2020 report conducted by Milliman, MA organizations serve a higher share of Medicare beneficiaries between ages 70 and 84 and a higher percentage of non-white beneficiaries than Traditional Medicare beneficiaries.[4] Older Medicare beneficiaries and beneficiaries of color should indisputably have equal access to the full slate of Medicare benefits, including the kinds of timely medical rehabilitation that can preserve functional abilities and an individual's ability to live as independently as possible and participate in community activities.

The misuse of prior authorization has long been a serious concern for CPR. Denials and delays in post-acute and rehabilitation care prevent individuals from receiving essential treatment to maintain or regain their health and function following an injury or illness or due to a disability or chronic condition. CPR concurs with CMS's assertion in the Medicare Advantage proposed rule (CMS-4201-P) that prior authorization should serve as a mechanism to confirm a diagnosis and determine appropriate clinical care, not as a systematic barrier to care. The use of prior authorization to approve care including medical rehabilitation services and devices, transplantation, non-elective surgeries, and cancer care is especially hard to justify, given that these and many similar medical services are unlikely to be over-utilized and often must be provided in a timely manner to maximize their medical efficacy. Delays in receiving medically necessary rehabilitation services, even if authorization is eventually approved, can have serious consequences for patients' long-term health and functional outcomes.

CPR's primary focus is ensuring that all patients, especially those with serious and complex conditions such as brain injury, stroke, multiple sclerosis, spinal cord injury, amputation, and other significant disabilities and chronic conditions are able to access the medically necessary care they need, in the most appropriate setting, in order to maintain and improve their health and function. Part of CPR's mission is to reduce the frequency of inappropriately delayed or denied rehabilitative care in a variety of post-acute care settings, particularly inpatient rehabilitation hospitals and units, commonly referred to as inpatient rehabilitation facilities or "IRFs."

CPR strongly supports the prior authorization regulations CMS proposes for impacted payers and urges the agency to finalize these provisions as expeditiously as possible—with modifications to strengthen the rule where necessary.

Prior Authorization Documents and Process

The proposed rule would require impacted payers to implement and maintain a Fast Healthcare Interoperability Resource (FHIR) Prior Authorization Requirements, Documentation, and Decision (PARDD) Application Programming Interface (API) to facilitate an electronic, more streamlined prior authorization process for providers than exists today. This system would allow a provider to query the payer's system to determine if prior authorization is necessary for an item or service as well as the documentation requirements.

[4] Catherine Murphy-Barron, et al., Comparing the Demographics of Enrollees in Medicare Advantage and Fee-for-Service Medicare, Milliman Report commissioned by the Better Medicare Alliance (Oct. 2020).

CPR supports the proposal for an automated process to increase transparency and ease the burden on providers requesting prior authorization on behalf of their patients.

The PARDD API would be beneficial to providers and patients in several ways. Overall, it would reduce the administrative hurdles for providers that result in unnecessary delays in access to patient care. Many insurers currently require providers to call or send documents via fax machine to process prior authorization requests. These outdated systems slow down the prior authorization process and can require additional staffing to fulfill a payer's requests, which further contributes to delays in patient care.

Another common issue for providers is determining which items or services require prior authorization and identifying the necessary documentation needed for approval. These requirements vary across payers and in many cases, it is difficult to identify whether an item or service needs prior authorization. In order to evaluate a prior authorization request, payers require information from providers such as test results; however, the required information is not consistent from payer to payer, nor is such information always readily available. Providers waste valuable time contacting payers for this information before services can be approved or prior authorization requests can be completed. The proposed rule would require impacted payers to list the necessary documents in the PARDD API. Having a centralized, electronic system containing all necessary information would significantly reduce the substantial burden for providers of prior authorization, speed up the process for patients and cut down on easily avoidable documentation errors and delays in care that stem from currently inefficient processes.

Streamlining provider workflow through an automated system is an essential element of improving care for patients. Administrative hurdles delay care for patients who are forced to wait days or weeks as providers navigate an inefficient and cumbersome process. The delays are not benign and can result in serious setbacks to patients needing rehabilitative care.

Reasons for Denial of Prior Authorization

The proposed rule would require impacted payers to provide a specific reason for prior authorization denials, regardless of the method used to send the request. Responses sent through the new automated system from the payer to the provider would have to include information about whether the payer approves the request, needs more information, or if the request is denied. If the request is denied, the proposed rule requires the payer to state the reasons for the denial. Existing regulations that require Medicaid managed care, CHIP, and Medicare Advantage plans to send a written denial notice would remain in place.

CPR strongly supports the proposed requirement to provide specific reasons for prior authorization denials and recommends CMS consider outlining specific definitions for and examples of terms such as "approval," "denial," and "specific reason for denial."

This proposed regulation would greatly benefit patients and providers in the medical rehabilitation sector, particularly IRF patients and providers. CPR frequently hears from patients who are denied prior authorization for care in an inpatient rehabilitation hospital without a specific reason for the denial. When an individual receives a denial that only cites that the item

or service is considered "medically unnecessary" by the payer, it is impossible to understand the true reason for the denial and makes appealing the decision more challenging. Vague phrases like "the patient could be treated in a less intensive setting" is not an appropriate reason for denial of an IRF stay and, yet this is a common reason that IRFs are not granted the ability to treat patients who otherwise qualify for this level of intensive rehabilitation care. Vaguely worded denials that lack specificity in their reasoning create barriers for providers and patients seeking to appeal the decision, particularly in urgent situations. In these opaque processes, the power rests entirely with the payer to provide further details so the provider can meaningfully address the denial reason. Providers and patients are left to speculate the reasons for denial instead of receiving a clear response that allows for a reasonable chance at appeal.

CPR strongly supports this proposal and seeks to ensure its application is meaningful. CPR encourages CMS to provide specific examples of the term "specific reasons" for denial cited in the proposed rule and, in the IRF context, to provide examples of denial reasons that would not be sufficient for payers to use without more detail from the clinical record. CMS should consider going further in the final rule by requiring payers to state what specific clinical, medical, or functional evidence would be sufficient to warrant an approval of a given service. This clarifying information is essential to individuals in need of rehabilitation services in IRFs who are denied prior authorization for "lack of medical necessity" and must appeal the decision quickly to avoid being sent to a lower level and clinically inappropriate setting of care as they await discharge from an acute care hospital.

We urge CMS to consider prescribing specific definitions of "approval" and "denial" since some payers amend the prior authorization request and approve only a portion of what the treating physician prescribes. For example, a provider might prescribe eight physical therapy sessions for a given patient submitting a prior authorization request. The payer may "approve" the request but only grant such approval for four physical therapy sessions, requiring that provider to submit another request for the same course of treatment. That decision is often considered an approval even though the payer denied the provider's request for an appropriate course of treatment. This comes as close to the payer practicing medicine as any utilization review technique and it should be prohibited by these final regulations.

This issue intersects with the Medicare Advantage proposed rule (CMS-4201) which would prevent MA plans from subjecting a patient to prior authorization for an ongoing treatment after an initial authorization for a "course of treatment" has been granted. As in the MA proposed rule, CPR hopes that CMS offers more detailed definitions in the final rule that clarify what defines a course of treatment. CPR would like to ensure that providers and patients are the decision makers for courses of treatment and that plans do not inappropriately label amended prior authorizations as "approvals" both in communication to providers and patients and in public reporting of prior authorization data.

Decision Timeframes for Prior Authorization

The proposed rule would require MA organizations, Medicaid Fee-For-Service (FFS) programs, and CHIP FFS programs 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.

CPR supports shorter timeframes for evaluating prior authorization requests and recommends that CMS consider a 24-hour timeframe for urgent requests and a 72-hour timeframe for non-urgent requests given the workflow solutions offered through this proposed rule and the proposed rule for Medicare Advantage plans (CMS-4201-P).

CPR commends CMS for recognizing that the timeframe for prior authorization decisions must be regulated. These timeframes can mean the difference between receiving the service in a timely manner and delaying or even denying access to care. This is particularly true in the IRF context. For instance, a typical candidate for IRF admission is identified at the acute care hospital after immediate and initial treatment to address an illness or injury. As the patient is prepared for a discharge from the acute care hospital, a clinical decision is made as to the next level of care that is necessary to complete the course of treatment to address patient needs. If the treating physician makes a referral to an IRF and a prior authorization request is required, the patient may wait multiple days for a decision on this admission. Such delays produce costs to payers for unnecessary acute care hospitalization, delays in access to the next, clinically appropriate level of care, and often result in discharges to lesser levels of care because the hospital can no longer wait for a payer to decide. Many times, payers do not operate on weekends and holidays, which create a scenario for gaming this process to avoid paying for more intensive or complex care.

Given this scenario, **CPR recommends CMS institute a shorter timeframe across all impacted payers for expedited or urgent requests and identify specific types of services that should always be considered for expedited review.** For patients in need of rehabilitation care, delays in receiving prior authorization can result in serious health consequences or even abandoning care at an appropriate level and intensity. The need for emergent or expeditious access to health care services takes place every hour of every day and medical care must be available to respond to those emergencies, including on weekends and holidays.

An urgent request for prior authorization should be evaluated by the end of the day in which the request was made but in no event more than <u>24 hours from the time of the request, whether or not the request is made on a Friday of a business week</u>. It is not appropriate for payers to decide a timeline for emergency medical care. Rather, those decisions should rest with trained providers treating patients in real time. We also note that many, if not all, rehabilitation services, particularly admissions to inpatient rehabilitation hospitals or other post-acute care settings from an acute care hospital, should qualify as urgent requests. The timeliness of access to an intensive rehabilitation program can have a profound impact on long term outcomes for patients. For these reasons, **CPR recommends shortening the timeframe for expedited prior authorization requests, requiring decisions to be made by payers on weekends and holidays, and requiring impacted payers to identify in the PARDD API which specific services qualify as expedited or urgent requests.**

For non-urgent requests, CPR recommends a shorter timeframe of 72 hours for payers to respond to requests, rather than the seven days proposed in the rule. CPR recognizes that payer approval within 24 hours is not necessary for all items and services. We also recognize that an approved prior authorization can help reduce the likelihood of a claim denial after services have been provided by the provider, forcing the patient and provider into an inefficient administrative appeals process that is often burdensome and time-consuming. Such appeals also take valuable time away from frontline providers who would be off spending time addressing current patient needs.

The shortened timelines we recommend are particularly appropriate given the additional changes intended to streamline prior authorization in this proposed rule and the Medicare Advantage proposed rule (CMS-4201-P). If the MA rule is finalized as proposed, payers would be prohibited from using internal coverage criteria that is stricter than Medicare FFS for items and services covered by Medicare. MA plans with supplemental benefits beyond Medicare FFS would be required to post publicly the prior authorization requirements for providers to see. Since the standards of prior authorization would be either consistent with Traditional Medicare or publicly available, evaluating prior authorization would be simplified for plans and providers. Also, providers can utilize the PARDD API to check requirements and deliver the correct documents quickly to payers through an electronic system without navigating phone calls and fax machines. Payers will be easily able to reference the documentation, consult established publicly available criteria, and render a decision. All these changes in the two proposed rules would streamline workflows and establish more efficient and responsive systems.

Public Reporting of Prior Authorization Metrics

The proposed rule would require impacted payers to publicly report certain aggregated metrics about prior authorization by posting them directly on the payer's website or via a publicly accessible hyperlink. The data would be reported at the organizational level for Medicare Advantage, at the state level for Medicaid and CHIP FFS, at the plan level for Medicaid and CHIP managed care, and at the issuer level for QHP issuers on the Federally Facilitated Exchange (FFE).

CPR strongly supports these data transparency requirements for all plans impacted by this rule. For an individual with a disability or chronic health condition seeking a new MA plan or QHP, for instance, that person would have the ability to research competing plans to assess their prior authorization practices before making a choice of plan. A publicly available resource would also serve to hold impacted payers accountable to enrollees, providers, and the public for its practices.

However, CPR urges CMS to require data reporting a more granular level than in an aggregated format, particularly setting-specific data. Only with this level of specificity will patients and providers be able to assess which services are routinely denied, appealed, and overturned in favor of patients and providers. CPR is concerned that prior authorization denials in the post-acute care sector are more common than in other settings, as has been recognized by the 2022 OIG report, and that these disparities in approvals would be concealed in an aggregated

data reporting requirement. A prospective enrollee or beneficiary will be able to make a more informed decision if they can compare multiple payers' prior authorization metrics at the setting of care level.

Enrollees and beneficiaries must be able to understand this information in order to act upon it. Therefore, **CPR recommends requiring impacted payers to present the data in a format that is easily accessible and readable for all enrollees, particularly individuals with disabilities and individuals with limited or low health and data literacy.**

Patient Access API

The proposed rule would add information about prior authorizations to the categories of data required to be made available to patients through the Patient Access API by impacted payers, no later than one business day after the payer receives the prior authorization request. The information would include related administrative and clinical documentation for items and services.

CPR supports CMS's efforts to enable patients to take an active role in their healthcare through information sharing. CPR strongly recommends CMS provide guidance on ensuring the Patient Access API is accessible and easy to use for individuals with disabilities and for individuals with limited or low health literacy.

Provider Access API

The proposed rule would require impacted payers to implement and maintain a Provider Access API to enable current patients' information to be exchanged from payers to providers that are in that payer's network, at the provider's request. Patients would need to opt out through a mechanism maintained by the payer.

CPR supports the streamlining of provider workflows to ease the burden on patients to coordinate the transfer of electronic health information by establishing a Provider Access API.

Payer-to-Payer API

The proposed rule would require impacted payers to establish and maintain a Payer-to-Payer API to ensure data can follow patients when they change payers. The Payer-to-Payer API would facilitate the creation of a longitudinal health record for patients and would expedite care and reduce unnecessary burden and duplication when patients change plans.

CPR supports this increased data sharing, with permission by the patient, to ease the burden on patients to coordinate health record exchanges when changing from one plan to another and to reduce the inefficiencies of methods like phone calls and fax machines to secure prior authorization approvals.

Enforcement Mechanisms

As stated throughout these comments, CPR greatly appreciates CMS' attention to solving critical issues in current prior authorization processes and CMS's proposals to ensure that beneficiaries

are able to access the medically necessary care to which they are entitled in a timely manner. These technological and system improvements will be a significant task for impacted payers to complete, implement, and maintain. CPR has concerns about the monitoring and oversight of impacted payers' adherence to these new standards. Therefore, we encourage CMS to consider detailing the expected enforcement mechanisms for these new requirements in the final rule, to ensure that beneficiaries are able to see the full impact of these proposals reflected in practice.

Immediate Reforms Needed

Most of the provisions in this proposed rule would take effect in January 2026 including reforms to prior authorization practices without technology requirements. While we recognize that the technological rollout of some provisions could require more time for development and testing, several of the most impactful provisions for patients could be implemented within the next 12 months, including shortening timeframes for prior authorization decisions, requiring specific reasons for denials of prior authorization, and reporting prior authorization metrics publicly. Three years is too long to wait for these reforms. As demonstrated throughout this letter, the misuse and overuse of prior authorization is an immediate and serious harm for patients, particularly for patients in rehabilitation settings. **We urge CMS to shorten the implementation timeframe for as many, if not all, provisions of this rule.**

We applaud CMS for recognizing the harms to beneficiaries posed by certain prior authorization practices and timeframes and the burdens placed on providers, and strongly encourage CMS to finalize this proposal and continue to guard against prior authorization as a mechanism to delay and deny medically necessary care, particularly for people with injuries, illnesses, disabilities, and chronic conditions that require rehabilitation care.

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We greatly appreciate your consideration of our comments on the *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule. Should you have any further questions regarding this information, please contact Peter Thomas or Joe Nahra, coordinators for CPR, by e-mailing Peter.Thomas@PowersLaw.com or Joseph.Nahra@PowersLaw.com, or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the Coalition to Preserve Rehabilitation

ACCSES
ADVION (Formerly the National Association for the Support of Long-Term Care (NASL))
Allies for Independence
ALS Association
American Academy of Physical Medicine and Rehabilitation
American Association on Health and Disability
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Occupational Therapy Association

American Physical Therapy Association
American Speech-Language Hearing Association
American Spinal Injury Association
American Therapeutic Recreation Association
Amputee Coalition
Association of Academic Physiatrists
Association of Rehabilitation Nurses
Center for Medicare Advocacy*
Child Neurology Society
Christopher & Dana Reeve Foundation *
Disability Rights Education and Defense Fund (DREDF)
Epilepsy Foundation
Falling Forward Foundation*
Lakeshore Foundation
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Association of Rehabilitation Providers & Agencies
National Association of Social Workers (NASW)
National Council on Independent Living
National Disability Rights Network (NDRN)
Spina Bifida Association
United Cerebral Palsy
United Spinal Association*

****CPR Steering Committee Member***