February 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: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4201-P)

Dear Administrator Brooks-LaSure:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs proposed rule*. Our comments focus on the sections of the proposed rule relating to improvements of utilization management tools employed by Medicare Advantage organizations.

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 for incorporating patient and provider feedback into the development of this rule. This rule requires numerous beneficiary protection improvements to Medicare Advantage plans that CPR has been seeking for many years on behalf of patients needing rehabilitative care. We believe this proposed rule is an important step forward in beginning to reform the overuse of utilization management, especially prior authorization, in the MA program and reducing the frequency of inappropriately delayed or denied rehabilitative care in a variety of post-acute care settings, particularly inpatient rehabilitation hospitals, commonly referred to as inpatient rehabilitation facilities or "IRFs". **CPR strongly supports the patient protection regulations CMS proposes and urges the agency to finalize these provisions as expeditiously as possible—with modifications to strengthen the rule where necessary.**

We strongly support CMS's commitment to reining in the egregious overreaches of Medicare Advantage plans. This proposed rule is a lifeline to the more than 28 million people enrolled in MA (nearly 50% of the eligible Medicare population) who are subjected to endless barriers to care, delays, and unjust denials for rehabilitation treatment and services. Medicare Advantage plans are making huge profits by servicing some of the most vulnerable patients, namely seniors and people with disabilities and chronic conditions—with little data that beneficiaries are receiving better care or experiencing better outcomes. 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 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.

In addition to advocating for increased access to rehabilitation services, we support the advancement of health equity and access to covered items and services for individuals with disabilities and chronic conditions. The populations our members represent frequently need assistive devices and technologies, including durable medical equipment (DME), orthotics, prosthetics, and other assistive devices and technologies, to meet their medical and functional needs. As with rehabilitation services, MA plans utilize prior authorization, proprietary and internal guidelines, and other coverage policies to restrict access to these items for individuals with medical and functional needs. We support the reforms included in this proposed rule and detail below our positions to ensure that all MA enrollees, regardless of their disability, injury, illness, chronic condition, or other needs are able to access the medical services and devices to which they are entitled under the Medicare benefit.

We are steadfast in our commitment to ensuring that patients do not needlessly face barriers to medically necessary care created by Medicare Advantage plans that overuse and misuse prior authorization. As such, CPR urges CMS to further detail in the final rule implementation,

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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. 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.

monitoring, and enforcement mechanisms that will make these reforms real for beneficiaries and hold MA organizations accountable to these patient-centered and equity-focused reforms to utilization management tools. Below, we address many of the agency's proposals in greater detail and offer our recommendations for strengthening these proposed reforms.

Utilization Management Tools

CPR strongly supports the proposed rule's provisions establishing guardrails around utilization management tools. 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. Unfortunately, many patients enrolled in MA plans face severe barriers to access for post-acute care, whether due to restrictive coverage policies, improper usage of prior authorization, or other administrative burdens. CPR has long held significant concerns about cost-cutting practices that MA plans deploy at the expense of the health and well-being of beneficiaries in need of services, likely impacting most severely patients with the highest level of medical and functional needs.

MA Plans Required to Follow Traditional Medicare Coverage Criteria for Basic Benefits

The proposed rule states that MA organizations must comply with all coverage guidance in Medicare manuals, National Coverage Determinations, and Local Coverage Determinations; they may not limit coverage through the adoption of utilization management and prior authorization policies and procedures. MA organizations would be prohibited from utilizing internal guidelines limiting or denying coverage when the item or service would be covered under Traditional Medicare, including for Skilled Nursing Facilities (SNF) care, Home Health services, and inpatient rehabilitation hospital services.

As nearly half of Medicare beneficiaries received their care under the Medicare Advantage program and more Medicare beneficiaries enroll in MA plans, it is critical that these individuals are able to access the same basic benefits as in Traditional Medicare. There are existing regulations that suggest that MA plans must provide the same benefits as Traditional Medicare, but this has not stopped MA plans from routinely imposing more restrictive coverage guidelines. Ensuring equal application of Traditional Medicare and MA benefits is especially important given the demographic comparison between Medicare enrollees in the MA program and those in Traditional Medicare.

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

[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).

benefits, including the kinds of timely rehabilitation that can preserve functional abilities and an individual's ability to live as independently as possible and participate in community activities.

This provision will greatly improve the health and well-being of MA patients in need of rehabilitation services, and CPR strongly supports CMS in its efforts to strengthen protections for patients. CPR recommends that MA organizations not be permitted to have additional internal coverage criteria for coverage of basic benefits.

Use of Proprietary Guidelines

In previous comments and letters to CMS, CPR has written about the issues with MA organizations not following Medicare coverage criteria for individuals in need of rehabilitation, particularly regarding coverage for IRF care. CMS has developed detailed coverage regulations for Medicare IRF coverage. Current regulations suggest that the same coverage rules apply to both Traditional Medicare and MA beneficiaries; however, in practice, many MA plans routinely ignore Medicare coverage regulations and deny inpatient rehabilitation admissions or divert patients to lower-acuity settings of care.

There are significant barriers under MA plans to patients accessing the post-acute, rehabilitative care they need. In our experience, many MA plans do not use Medicare IRF coverage criteria when determining coverage for IRF care. Instead, these plans apply private, proprietary decision support tools, including Milliman and InterQual guidelines ("non-Medicare guidelines"), to make their decisions as to which rehabilitation setting is covered for each patient. These practices tend to systematically divert Medicare beneficiaries to less intensive rehabilitation settings than they are entitled to under the Medicare program, potentially risking the health and functional potential of Medicare MA beneficiaries. In fact, MedPAC has stated that MA beneficiaries receive one third the level of access to IRF care than Traditional Medicare beneficiaries.[5]

In this proposed rule, CMS explicitly proposes to require that MA organizations cannot deny authorization of services based on internal criteria or proprietary guidelines that go beyond Traditional Medicare coverage rules. This would include guidelines that restrict access to covered items or services unless another item or service is furnished first, unless such progression is specifically required in a National Coverage Determination (NCD) or a Local Coverage Determination (LCD). **CPR strongly supports this proposal and urges CMS to finalize it as expeditiously as possible.**

The proposed rule implements guardrails around Part A and Part B benefits offered by MA plans that do not have applicable Medicare NCDs, LCDs, or other specific Medicare coverage criteria in regulation. When a given item or service is not explicitly governed by an existing Medicare coverage policy, MA organizations would be required to make their coverage criteria public, including a summary of the evidence that was considered during the development of internal criteria, a list of high quality evidence informing the decision, and an explanation of the rationale for the new coverage criteria. **CPR strongly supports the transparency requirements and**

[5] Medicare Payment Advisory Commission, Report to The Congress: Medicare Payment Policy 298 (Mar. 2017).

urges CMS to finalize as expeditiously as possible. In fact, CPR would welcome processes to further enhance transparency when MA plans supplement Traditional Medicare coverage criteria with their own coverage standards.

The proposed rule also states that CMS does not plan to require MA organization to provide a pre-determination explanation and opportunity for the public to comment on the MA organization's coverage criteria. **CPR recommends that CMS consider requiring a public comment period for any MA plan coverage criteria to allow for full consideration of the evidence and rationale by patients and providers.** Patient groups and providers are concerned that MA plans will continue to utilize proprietary decision support tools to make decisions about rehabilitation care to the detriment of people in dire need. A public notice and comment process would shine additional light on the quality of the evidence used to implement more detailed coverage policies by MA plans.

CPR has long raised serious concerns about the impact of proprietary guidelines on patient access to care. These guidelines frequently serve as a mechanism for MA plans to override the clinical judgment of treating physicians and rehabilitation care teams, effectively ignoring Medicare's coverage regulations. Prohibiting the use of such criteria and ensuring transparency when existing Medicare coverage guidelines are not applicable, will be a critical victory for patients who seek coverage and payment for the medically necessary services to which they are entitled.

Medical Necessity Determination Guidelines

The proposed rule codifies existing medical necessity determination guidelines into regulation, including:

1) a provision that MA organizations may not deny coverage for basic benefits based on coverage criteria not found in § 422.101(b) and (c);

2) MA organizations are required to consider whether the item or service is reasonable and necessary under 1862(a)(1);

3) MA organizations must consider an enrollee's medical history; and

4) MA organizations' medical directors must be involved.

CPR supports this proposal and urges CMS to consider further measures to protect enrollees.

CMS also proposes to update the agency's existing reviewer standards to require that the physician or other health care professional conducting the review must have expertise in the field of medicine that is appropriate for the item or service being requested before a plan can issue an adverse decision. **We strongly support this proposal and urge CMS to strengthen this provision.** Often, a rehabilitative medicine physician recommends clinically appropriate care for an MA patient, but that care is denied for lack of medical necessity because the medical director (or more commonly, the non-physician staff of the MA plan) reviewing the request is not trained in rehabilitative medicine. It is a significant burden on rehabilitation providers to educate and

explain clinical care within their specialty to an MA organization medical director (or non-physician staff) when those decision-makers do not have the experience or training to adequately understand the medical necessity of the care being prescribed. It is essential that the medical directors (and their non-physician clinical staff) of the MA plan are appropriately trained in directly related specialties to determine medical necessity.

We note that this proposal does not require the reviewing provider to be of the same specialty or subspecialty as the treating physician, and that plans would have discretion to determine on a case-by-case basis what constitutes "appropriate expertise" based on the relevant circumstances. We understand that reviewers may have some expertise in a field without a specialty or subspecialty certification. However, we urge CMS to add more specific guardrails to ensure that appropriately qualified reviewers are involved in decision-making around coverage for particularly complex services, including post-acute care.

For example, CMS already details requirements for IRFs to be led by a rehabilitation physician, the definition of which does not specify a particular certification. Instead, the regulations require rehabilitation physicians to have specialized training and experience in IRF care. We believe a similar requirement should be applied to MA plans when reviewing the appropriateness of an admission to an IRF or prescription of other rehabilitation services. When a plan is seeking to override the clinical judgement of a rehabilitation physician with specialized training and experience in rehabilitation who has prescribed a particular item or service for an individual in need of post-acute care, this determination should be made only by a similarly qualified physician representing the plan. MA plans should provide deference to these physicians unless there is evidence in the patient record that specifically contradicts the physician's medical necessity determination.

Appropriate Use of Prior Authorization

The proposed rule states that prior authorization should only be used to confirm the presence of diagnoses or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically appropriate. **CPR strongly agrees with CMS's proposal that prior authorization should not be used to delay or deprive care to beneficiaries for which they otherwise qualify.**

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 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, preventing beneficiaries in the MA program from receiving the treatment they need in order to regain and/or maintain their health and function following injury, illness, disability, or chronic condition.

As demonstrated in the previously referenced OIG report from April 2022, many plans utilize prior authorization processes to delay or deny approval for items and services that meet Medicare

coverage rules and/or are, in the end, routinely approved.[6] These findings echo previous figures reported by OIG, including the finding that when beneficiaries and providers appealed initial denials, MA plans overturned their own denials 75% of the time.[7] Post-acute care services, particularly admission to IRFs and skilled nursing facilities (SNFs), were among the most prominent types of frequent denials through the use of prior authorization.

Additionally, the use of prior authorization to approve care including 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 needed to 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 outcomes.

We applaud CMS for recognizing the harms to beneficiaries posed by the overuse and misuse of prior authorization, 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 in the MA program.

Pre-Service Determinations

The proposed rule codifies existing guidance that prevents MA organizations from denying coverage or payment based on medical necessity if a patient requested and received a pre-service approval. **CPR strongly supports this common-sense proposal that protects MA enrollees from predatory practices that can leave enrollees with hefty medical bills after services have been provided and urges CMS to finalize it as expeditiously as possible.**

Prior Authorization Continuity through Treatment Course

The proposed rule prevents MA plans from subjecting a patient to prior authorization for an ongoing treatment after an initial authorization has already been granted. **CPR strongly supports this rule and recommends CMS to consider additional guidelines to strengthen its protective measures.**

There is a broad trend towards limiting access to post-acute care for people in need of rehabilitation services through utilization management tools. One method of limiting access employed by MA organizations is subjecting enrollees to multiple rounds of prior authorization for the same course of pre-approved plan of care or ongoing treatment. Our members have heard from patients, especially those with severe and complex rehabilitation needs, that they are unable to achieve a full inpatient stay that is long enough to address their needs due to repeated prior authorization requests and denials.

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[6] 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).

[7] 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).

Another method of limiting access employed by MA organizations is through extended administrative delays in the process of obtaining prior authorization. The timeliness of prior authorization requests is addressed more thoroughly in CMS's Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (CMS-0057-P), but timeliness is a critical issue in utilization management tools. Our members have heard from patients of repeated prior authorization processes that are extended indefinitely as a result of "administrative delays" by the MA organization. We hope that administrative delays will be alleviated through the combined transparency requirements of this rule, prohibition of proprietary coverage guidelines, and the timeliness expectations in the CMS-0057-P rule.

CPR is concerned about the definition of "course of treatment," particularly the potential for plans to exploit the definition by segmenting treatment into multiple smaller "courses" to utilize prior authorization as a barrier to care. For example, if a patient is prescribed a course of physical, occupational, or speech therapy after an injury intended to last six weeks, a plan should not be able to offer prior authorization only for 3-4 visits at a time. Similarly, approving an IRF stay 3 days at a time, for instance, interrupts the treatment plan and compromises the ability of providers to deliver a comprehensive rehabilitation program in a timely and efficient manner. In the rule, course of treatment is defined as "a prescribed order or ordered course of treatment for a specific individual with a specific condition, as outlined and decided upon ahead of time, with the patient and provider." CPR would like to ensure that providers and patients are the decision makers for course of treatment and that MA plans do not utilize "course of treatment" as a tool of delaying care for patients.

CPR strongly supports this proposal and urges CMS to finalize it as expeditiously as possible and to consider additional guidelines to ensure the final provision is fully implemented and enforced as intended.

90-day Transition Period

The proposed rule would require MA plans to provide a minimum 90-day transition period when an enrollee currently undergoing authorized treatment switches to a new MA plan, even if the course of treatment was for a service with an out-of-network provider.

CPR strongly supports this proposal to guarantee a 90-day transition period for patients switching from one MA plan to another. Throughout the proposed rule, CMS has made it clear that the function of prior authorization is to confirm the presence of a diagnosis that ensures the medical necessity or clinical appropriateness of a service or benefit. The standards of prior authorization must be consistent across all MA plans, particularly with respect to the scope of benefits covered by Traditional Medicare. It would be redundant for an MA organization to request a new prior authorization process when another MA plan, providing benefits under the same coverage requirements, has already authorized a patient's course of treatment.

Not only would requiring another round of prior authorization be unnecessary from a medical perspective, but it would subject patients and providers to another burdensome approval process. It places an unnecessary burden on enrollees and their providers to obtain duplicative prior authorization approvals for treatment for which they have already submitted the appropriate

documentation and have been approved for coverage. For patients in need of rehabilitation, potential delays in care caused by switching plans could have serious, long-term consequences for their health and recovery process.

Enforcement Mechanisms

As stated throughout these comments, CPR greatly appreciates CMS' attention to our long-held concerns about the misuse of utilization management techniques by MA plans and the proposals to ensure that MA beneficiaries are able to access the medically necessary care to which they are entitled. We also note that several of these requirements already exist in subregulatory guidance, yet the agency has clearly recognized the need to codify and re-emphasize these requirements due to non-compliance by MA plans. 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.

Network Adequacy

In the proposed rule, CMS includes several proposals to update network adequacy standards for MA plans, largely focused on behavioral health. In previous years, CMS has also revised the time and distance standards as well as the list of provider and facility specialty types subject to network adequacy reviews. CMS does *not* currently include post-acute rehabilitation programs, including inpatient rehabilitation hospitals and units (IRFs), comprehensive outpatient rehabilitation facilities (CORFs), and long-term acute care hospitals (LTCHs) in the list of facility specialty types evaluated during these reviews. These are critical settings of care for patients in need of rehabilitation services and devices, and their omission in network adequacy reviews is glaring. This is illustrated by the fact that CMS includes IRFs, CORFs, and LTCHs as a covered benefit under traditional Medicare, and hundreds of thousands of Medicare enrollees benefit from treatment offered by these providers on an annual basis. **CPR strongly urges CMS to include IRFs, CORFs, and LTCHs as part of the agency's network adequacy review process for MA plans.**

Health Equity and Accessible Format Requirements

CPR supports CMS's proposal to require MA organizations to provide appropriate and accessible materials for enrollees and include providers' cultural and linguistic capabilities in directories. It is essential that all enrollees be able to access important information about their health coverage, benefits, and obligations, and CPR has been concerned about recent reports regarding the hurdles individuals with disabilities face in receiving accessible communications. In particular, we thank CMS for clarifying that MA plans must honor requests for communications to be provided in accessible formats not on a case-by-case basis, but for all future communications unless the request for accommodations is changed by the beneficiary. This is a common-sense requirement that, if finalized and enforced, will enable beneficiaries to have basic interactions with their health plan without undue burden.

Marketing Restrictions

CPR strongly supports the patient protection rules for marketing of MA plans. Predatory marketing is serious problem for seniors and people with disabilities eligible for Medicare, often leading individuals to select a plan that would not provide necessary services.

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We greatly appreciate your consideration of our comments on the Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs 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))
ALS Association
American Academy of Physical Medicine & Rehabilitation
American Association on Health and Disability
American Association of People with Disabilities
American Congress of Rehabilitation Medicine
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
Association of Academic Physiatrists
Association of Rehabilitation Nurses
Association of University Centers on Disabilities
Brain Injury Association of America *
Center for Medicare Advocacy *
Christopher & Dana Reeve Foundation *
Clinician Task Force
Disability Rights Education and Defense Fund
Epilepsy Foundation
Falling Forward Foundation *

Lakeshore Foundation
Muscular Dystrophy Association
National Association for the Advancement of Orthotics and Prosthetics
National Association of Rehabilitation Providers and Agencies
National Association of Social Workers (NASW)
National Disability Rights Network (NDRN)
National Multiple Sclerosis Society *
Rehabilitation Engineering and Assistive Technology Society of North America
Spina Bifida Association
Uniform Data System for Medical Rehabilitation
United Cerebral Palsy
United Spinal Association *

****CPR Steering Committee Member***

<u>Additional Supporting Organizations</u>

AdvaMed
American Association for Homecare
American Cochlear Implant Alliance
American Council of the Blind
American Macular Degeneration Foundation
Blinded Veterans Association
The Buoniconti Fund to Cure Paralysis
Institute for Matching Person and Technology
Long Island Center for Independent Living
Medical Device Manufacturers Association
Miami Project to Cure Paralysis
National Registry of Rehabilitation Technology Suppliers
The Simon Foundation for Continence
Team Gleason
The Viscardi Center
VisionServe Alliance