January 27, 2025

ELECTRONIC SUBMISSION VIA www.regulations.gov

The Honorable Jeff Wu
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CPR Comments on the CY 2026 Medicare Advantage and Medicare Part D Proposed Rule (CMS-4208-P)

Dear Acting Administrator Wu:

The undersigned members of the Coalition to Preserve Rehabilitation ("CPR") appreciate the opportunity to submit comment to the Centers for Medicare and Medicaid Services ("CMS") in response to the Contract Year ("CY") 2026 Medicare Advantage and Medicare Part D Prescription Drug Benefit Programs Proposed Rule ("Proposed Rule"), which was published in the Federal Register on November 26, 2024. We offer our recommendations and comments below regarding various provisions in the proposed rule impacting beneficiaries in need of medical rehabilitation care.

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 must navigate the complexities of both Traditional Medicare and Medicare Advantage ("MA") in order to receive quality health care, and we appreciate CMS's goal of streamlining and aligning the two aspects of the program where appropriate.

This Proposed Rule builds on the substantial changes implemented in the CY 2024 Medicare Advantage Program final rule (hereinafter referred to as the "April 2023 final rule"), which went into full effect on January 1, 2024. CPR wishes to again commend CMS for finalizing those regulations that addressed serious beneficiary and provider concerns with MA plans' use of utilization management tools, particularly prior authorization and clinical algorithms to determine coverage, and establishing new policies limiting an MA organization's ability to deny or limit coverage of basic benefits as covered under Traditional Medicare.

Our comments to the CY 2026 proposed rule focus on the sections of the draft regulation relating to requirements for plan use of internal coverage criteria, proposed revisions to the required metrics for the annual health equity analysis pertaining to the use of prior authorization, guardrails for the use of artificial intelligence ("AI") to protect access to health services, and the proposed expansion in access to transformative anti-obesity medications under the Medicare Part D and Medicaid programs.

I. Enhanced Rules on Internal Coverage Criteria

In the April 2023 final rule, CMS codified regulations that clarified the obligations and responsibilities of MA organizations to develop and use coverage criteria in a way that aligns with Traditional Medicare. Specifically, CMS clarified that statutes and regulations that set the scope of coverage in the Traditional Medicare program are applicable to MA organizations in setting the scope of benefits that must be covered by MA plans. CMS also codified requirements for making medical necessity determinations, which includes using applicable coverage criteria in Traditional Medicare laws, CMS's national coverage determinations ("NCDs"), applicable local coverage determinations ("LCDs"), and—when Traditional Medicare coverage criteria are not fully established—internal coverage criteria. CMS also codified specific requirements that determine when MA organizations may use internal coverage criteria, the quality of evidence on which the criteria is based, and rules for making the internal coverage criteria accountable and publicly accessible. These rules were applicable for coverage decisions made by MA organizations beginning January 1, 2024.

To further clarify these new requirements, CMS is proposing to build upon and enhance the regulations from the April 2023 final rule, specifically those related to the use of internal coverage criteria, by defining the meaning of "internal coverage criteria," establishing policy guardrails to help ensure patient access to benefits and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

Definition of Internal Coverage Criteria: In the April 2023 final rule, CMS codified that MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs, or LCDs. CMS further defined what it meant by "coverage criteria are not fully established" and "publicly accessible," but did not provide a definition of "internal coverage criteria."

Accordingly, CMS is proposing to define internal coverage criteria as:

> "any policies, measures, tools, or guidelines, whether developed by a MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by a MA organization for purposes of making a medical necessity determination."

Similarly, CMS explains that internal coverage criteria may not include any coverage criteria that restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care. **CPR**

supports these proposals that build on the April 2023 final rule to further increase health equity and transparency in MA plans with the ultimate goal of increased access to covered items and services for individuals with disabilities and chronic conditions, particularly rehabilitation services and related assistive devices provided in a variety of health care settings.

In analyses of MA plans' use of prior authorization, government agencies and private organizations have found serious misuse and abuse of prior authorization processes used by MA plans, in particular, how frequently MA plans require and deny prior authorization requests and shift the burden of securing covered items and services onto vulnerable beneficiaries—and their providers—who must appeal these denials. The misuse and abuse of prior authorization by MA plans to deny basic benefits is still a serious concern, particularly for Medicare beneficiaries in need of timely and intensive rehabilitation services.

The beneficiaries CPR member organizations represent frequently need assistive devices and technologies, including durable medical equipment ("DME"), orthotics, prosthetics, and supplies to meet their medical and functional needs. MA plans continue to extensively utilize prior authorization, proprietary and internal guidelines, and other coverage policies that have the effect of restricting access to these items for individuals with medical and functional needs. **CPR firmly believes that implementation of CMS's proposed definition of internal coverage criteria would increase public oversight of prior authorization policies employed by MA organizations.** We continue to be supportive of CMS's increased focus on health equity under the MA program 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, particularly rehabilitation services and devices, to which they are entitled under the Medicare benefit.

Public Availability: CMS is proposing to add more structure and detail to the public accessibility requirements to ensure that MA organizations are making their internal coverage criteria available in a manner that is routinized and easy to follow. Specifically, CMS is proposing that by January 1, 2026, MA organizations must publicly display on the MA organization's website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions. CPR supports this proposal.

Additionally, the MA organization's internal coverage criteria webpage must be displayed in a prominent manner and clearly identified in the footer of the website. The webpage must also be easily accessible to the public, without barriers, including but not limited to ensuring the information is available free of charge, without having to establish a user account or password, without having to submit personal identifying information, in a machine-readable format with the data contained within that file being digitally searchable and downloadable, and must include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access. CMS believes that by making this information more easily available, it will help third parties and researchers conduct studies to examine the clinical value of the internal coverage criteria being used by MA plans.

In addition to the public posting of this content, CMS is considering a requirement that MA plans annually report this information to CMS. CMS believes this information is critical to ensuring appropriate access to Part A and Part B benefits in the MA program and that there is value in comparing use of internal coverage criteria across all MA organizations. CMS notes that it would specify the format and collection of this information through the normal Paperwork Reduction Act ("PRA") process. Furthermore, CMS is soliciting comment on whether the Agency should require a specific format for the information posted on the MA organization website and whether a standard template for the posted information would be helpful.

CPR members, both beneficiaries and providers, support these new proposals to increase transparency from MA plans to ensure they are making their internal coverage criteria easily accessible to the public. Far too often, CMS will make data publicly available, but then make it difficult for the average enrollee, yet alone someone with a physical, mental or cognitive disability, to access it. CPR commends CMS for this proposal to simplify and streamline the availability of this important information and we agree that it will allow for better assessment of the clinical value of the internal coverage criteria being used by MA plans, which is critically important. **We would also encourage CMS to review the number of steps required to access this information and streamline those steps as much as possible to make it easier on the general public to get the information they need to make informed decisions. CPR also supports CMS's proposed requirement for MA plans to annually report this information.** We believe this annual reporting will lead to both greater accountability by MA plans and better understanding on behalf of CMS of the use of internal coverage criteria across all MA organizations. CPR encourages CMS to finalize these proposals as soon as possible.

II. Health Equity Analyses of Utilization Management Policies and Procedures

CMS is proposing to revise the required metrics for the annual health equity analysis pertaining to the use of prior authorization to require that such metrics are reported by each item or service, rather than aggregated for all items and services. The background on this issue is important to consider.

In the April 2023 MA final rule, CMS finalized a requirement that the Utilization Management committee must conduct an annual health equity analysis of the use of prior authorization. The analysis must examine the impact of prior authorization at the plan level, on enrollees with one or more of the specified social risk factors ("SRF"). The analysis must use the outlined metrics, aggregate them for all items and services, calculate them for enrollees with the specified SRFs, and compare them to enrollees without the specified SRFs from the prior contract year.

During the comment period of the proposed rule, CMS received a significant number of comments on the issue of aggregating data derived from the metrics for all items and services. Commenters, including CPR, recommended that CMS require a further level of granularity to help ensure that potential disparities could be identified. Specifically, commenters suggested that CMS require disaggregation by item and service to ensure that CMS can identify specific services that may be disproportionately denied. Nonetheless, CMS issued a final rule that allowed aggregation of prior authorization metrics for all items and services. We believe this does not provide enough detail for true accountability. However, CMS is now proposing to

revise the required metrics for the annual health equity analysis pertaining to the use or prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services.

CPR is pleased to see this proposal included in this year's proposed rule as this represents a positive step on behalf of CMS to further reign-in the overreaches of MA organizations that employ utilization management tools that inappropriately delay and deny care to beneficiaries. We continue to support more publicly available data focused on approvals/denials of services or devices for enrollees with disabilities and chronic conditions in order to hold MA plans accountable for discriminatory policies and practices.

CPR remains concerned that prior authorization denials in the post-acute care sector (e.g., inpatient rehabilitation hospitals and units ("IRFs"), skilled nursing facilities ("SNFs"), and home health care ("HHC")) are more common than in other settings, as has been recognized in the 2022 Office of the Inspector General report.[1] These disparities in prior authorization approvals are concealed in an aggregated data reporting requirement.

Post-acute care is essential for people with disabilities, illnesses, injuries, and chronic conditions to receive timely and often intensive medical rehabilitation services, and the well-documented denials of care for this at-risk population demands further examination. Under the current proposal, CMS would significantly improve health equity for beneficiaries by requiring more granular analysis at the level of items and services, particularly examining beneficiary access to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) instead of aggregating data for all items and services. **In fact, the CPR Coalition would support the disaggregation of DMEPOS data to report prior authorization metrics for DME separately from prosthetics, and separately from orthotics, as each of these benefits serves very different clinical purposes and is provided by very different clinicians and suppliers**.

The collection of more granular, setting-specific data will allow CMS to be able to view a much more comprehensive picture of patient satisfaction under the MA program, resulting in the agency's ability to better compare multiple payers' prior authorization metrics at the service line level. Moreover, requesting data that extends back over several contract years for these areas of care that are particularly needed by people with disabilities and chronic conditions will further illuminate longstanding discriminatory patterns of denials of care. Only with this more granular level of specificity will CMS be able to assess which services are routinely denied, appealed, and overturned in favor of patients and providers.

III. Guardrails for Artificial Intelligence ("AI")

Given the growing use of AI within the healthcare sector, such as, but not limited to, AI-based patient care decision support tools, vision transformer-based AI methods for lung cancer imaging applications, and AI and machine learning-based decision support systems in mental health care

[1] 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).

settings, CMS believes it is necessary to ensure that the use of AI does not result in inequitable treatment, bias, or both, within the healthcare system.

Accordingly, CMS is proposing to revise current regulations to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. CMS is also clarifying that in the event that a MA plan uses AI or automated systems, it must comply with applicable regulations and requirements and provide equitable access to services and not discriminate on the basis of any factor that is related to the enrollee's health status, including on the basis of disability. **Historically, one of the major drivers of inaccessibility was the lack of clarity as to what accessibility actually entails, which is why CPR supports and is grateful for the proposed guardrails on the use of AI under the MA program that are included in this proposal**. These proposed guardrails will certainly help to ensure that individuals do not face discriminatory barriers with AI's increased reliance in the healthcare setting.

IV. Network Adequacy

Currently, MA plans must ensure that beneficiaries have sufficient access to certain provider and facility specialty types within their networks, including time and distance standards. However, while SNFs, acute care hospitals, and inpatient psychiatric facilities are among the included providers in MA network adequacy standards, IRFs, comprehensive outpatient rehabilitation facilities ("CORFs"), and long-term acute care hospitals ("LTCHs") are ***not*** included in these standards. These are critical settings of care for patients in need of timely and intensive 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 has raised this issue with CMS in multiple comment letters over the past decade or more but our position has been seemingly ignored. **CPR strongly urges CMS to include IRFs, CORFs, and LTCHs as part of the agency's network adequacy review process for MA plans.**

V. Proposed Coverage of Anti-Obesity Medications

CMS is proposing to reinterpret current law to permit coverage under the Medicare and Medicaid programs of anti-obesity medications ("AOMs") for the treatment of obesity when such drugs are indicated to reduce excess body weight and maintain long-term weight reduction for individuals with obesity. This would be an expansion in coverage of AOMs as Medicare Part D and Medicaid currently cover certain AOMs when used to treat chronic conditions such as diabetes or heart disease. CMS believes that, in finalizing its proposal, the agency would be aligned with existing policies under which CMS permits Part D coverage for other drugs that would otherwise be excluded when they are being used to treat certain specific diseases (e.g., drugs used to treat acquired immunodeficiency syndrome ("AIDS") wasting and cachexia).

This proposed revised interpretation would recognize obesity to be a chronic disease based on changes in medical consensus. However, it is important to note that CMS would not consider that interpretation to extend to individuals who are overweight but do not have obesity, as

overweight is not considered a disease. A lack of mobility in the disability population contributes to obesity and the chronic illnesses that often accompany obesity. The reasons that some individuals with disabilities have difficulty managing their weight are multifactorial and include a lack of access to accessible fitness facilities, lack of coverage of assistive devices to perform specific exercises to maintain fitness and manage weight, and medical limitations on the ability to participate in rigorous exercise given one's disabling condition.

CPR firmly believes that all individuals living with obesity should have equal access to the full continuum of obesity treatment options available to those living with chronic diseases such as diabetes and cardiovascular conditions. The proposed expansion of AOM coverage under Medicare and Medicaid would provide, for the first time, individuals living with a disability with greater access to the anti-obesity care they may need to improve their health and lower the chances of developing—or reversing—associated chronic conditions. **For individuals with disabilities, coverage of these medications would add an important tool to use in the effort to assist in the reduction of body mass which, in turn, could lead to improvements in function and independence.** As a result, this would help motivate individuals to regulate their own weight and achieve greater benefit from rehabilitation therapies and assistive devices and technologies. Accordingly, we are fully supportive of CMS's proposal to expand coverage of AOMs under Medicare and Medicaid, and we urge the Agency to finalize this proposal as expeditiously as possible.

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We greatly appreciate your consideration of our comments on the CY 2026 Medicare Advantage and Medicare Part D Prescription Drug Benefit Program Proposed Rule. Should you have any further questions regarding this information, please contact Peter Thomas and Michael Barnett, CPR co-coordinators, by e-mailing Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the Coalition to Preserve Rehabilitation

ACCSES
ADVION
ALS Association
American Academy of Physical Medicine & Rehabilitation
American Association on Health and Disability
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
Brain Injury Association of America*
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Disability Rights Education and Defense Fund (DREDF)
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National Multiple Sclerosis Society*
RESNA
Spina Bifida Association
United Cerebral Palsy
United Spinal Association*

**** Indicates CPR Steering Committee Member***