AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

Submitted Electronically

November 12, 2024

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-10913

Re: Agency Information Collection Activities; Proposed Collection; Comment Request – Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request (CMS-10913)

Dear Administrator Brooks-LaSure:

On behalf of the American Medical Rehabilitation Providers Association (AMRPA), we write to offer our comments on the Centers for Medicare & Medicaid Services' (CMS) proposed *Information Collection Request on Medicare Part C Utilization Management Annual Data Submission & Audit Protocol Data Request* (CMS-10913), published in the *Federal Register* on September 10, 2024. AMRPA is the national trade association representing nearly 800 freestanding inpatient rehabilitation hospitals and rehabilitation units of general hospitals, referred to as inpatient rehabilitation facilities (IRFs). Our members focus on the medical care and functional recovery of some of the most vulnerable Medicare beneficiaries – such as traumatic brain injury, stroke, and spinal cord injury patients. AMRPA member hospitals help patients maximize their health, functional ability, independence, and participation in their communities, so they are able to return to home, work, or an active retirement.

IRFs play a unique and critical role in providing hospital-level medical and rehabilitation care to beneficiaries in Traditional (Fee-for-Service) Medicare and those enrolled in Medicare Advantage (MA) plans. Unfortunately, many individuals face significantly reduced access to inpatient rehabilitation care in the latter program[1], and we have long urged CMS to ensure that all beneficiaries maintain appropriate access to medically necessary covered benefits regardless of their chosen form of Medicare coverage. Meaningfully increasing transparency within the MA program regarding access to care and utilization management has been a key priority for AMRPA and our member hospitals in recent years. We appreciate CMS' focus on advancing data collection through this proposal and other recent actions so that patients, providers, and

[1] *See, e.g.,* Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy 298 (March 2017) (finding that MA beneficiaries have one-third the access to IRF care than Traditional Medicare beneficiaries).

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policymakers have the information they need to address concerns with MA program practices and so that beneficiaries can make fully informed decisions as to their Medicare coverage options.

I. CMS Proposed Information Collection

Under this proposed Information Collection Request (ICR), CMS seeks to (1) expand the annual reporting requirements for organizations sponsoring or offering Medicare Advantage health plans ("MA organizations") regarding their use of internal coverage criteria (also known as proprietary guidelines); and (2) detail expanded reporting requirements and compliance standards relating to internal coverage criteria for those MA organizations selected for utilization management (UM) audit activities. CMS proposes that this "universe" of data will help inform the agency's selection of sponsoring organizations that will be audited for their UM activities. For all MA organizations, CMS proposes to collect, on an annual basis:

- A list of each item or service for which the organization utilizes internal coverage criteria for rendering medical necessity determinations;
- The date of the most recent approval by the UM Committee for each set of criteria used;
- The application of each criteria (including the states and localities where they are used and which contracts they are used for);
- The organization or vendor developing any criteria used; and
- A direct website link where the criteria can be found, in accordance with the requirement that any such criteria be made "publicly accessible."[2]

During the agency's annual audit of MA organizations, CMS proposes to select a list of targeted items and services (up to 20 each year) for which CMS would more closely scrutinize plans' administration of benefits, especially focusing on the use of internal criteria. MA organizations selected for audits would be subject to much more stringent data submission protocols, with plans submitting information for each of the targeted items or services identified by CMS. These data elements include:

- Whether the organization considers the coverage criteria for each item or service to be fully established by CMS[3] (and if so, in which localities);
- All Medicare regulations, National Coverage Determinations, and Local Coverage Determinations applicable to the item or service;
- If the organization considers the coverage criteria not fully established, whether the organization determined this was because there were no applicable Medicare rules, because the applicable coverage rules require additional interpretation, or because applicable coverage rules explicitly allow flexibility in determining medical necessity;
- Identification of all internal coverage criteria or guidelines used for each targeted item or service, as well as the full specific criteria or tools used (to be reviewed by CMS auditors);

[2] 42 C.F.R. § 422.101(b)(6)(ii).
[3] As defined in 42. C.F.R. § 422.101(b)(6)(i).

- For all internal criteria used, the specific clinical evidence (widely used treatment guidelines or clinical literature) used to develop or support the criteria and a "unique and specific statement" as to how those criteria provides a clinical benefit highly likely to outweigh clinical harms;
- Details on the organization's UM Committee's review and approval of the criteria, including specific documentation, meeting minutes, and notes;[4] and
- For those internal criteria used, plans would be required to detail the specific steps that beneficiaries, providers, and non-members must take to access the plan's internal criteria online (including navigation and any information that needs to be submitted or user accounts created).

Finally, if and when an audit identifies plan non-compliance with existing UM requirements, the MA organization will be required to submit "Impact Analyses" upon request, detailing the specific services and items for which medical necessity determinations were made reliant on inappropriate internal coverage criteria. This would include an accounting of the total number of initial determinations, denials, reconsideration requests, and reconsideration request denials for that item and service.

II. Importance of Auditing Plan Use of Internal Coverage Criteria

As the burden of prior authorization and other utilization management tactics by MA organizations has grown in recent years, especially with regards to inpatient rehabilitation admissions, AMRPA and many other allied organizations have long called for greater transparency regarding plans' use of these practices and their impact on patient access to care. These concerns have been amplified by data indicating the high rates of denials that beneficiaries face when seeking IRF and other post-acute care admissions, most recently with a Senate investigative report finding that the nation's largest MA insurers deny post-acute care at dramatically higher rates than other services, including the majority of requests for IRF admissions.[5] The same report highlighted concerns around the increasing use of artificial intelligence, algorithms, and other "predictive technologies" in making coverage decisions; it is critical that these be considered within the scope of internal coverage criteria for purposes of the collections and audits proposed here by CMS.

[4] As required by 42 C.F.R. § 422.137(d).

[5] U.S. Senate Permanent Subcommittee on Investigations, Majority Staff, *Refusal of Recovery: How Medicare Advantage Insurers Have Denied Patients Access to Post-Acute Care* (Oct. 17, 2024). https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf

We greatly appreciate CMS' recent flurry of activity in this area, including the 2024[6] and 2025[7] MA final rules and the "electronic prior authorization" final rule issued in early 2024[8], but have serious concerns that new requirements have yet to be sufficiently enforced. This is particularly relevant with regards to the regulations around the use of internal coverage criteria or proprietary guidelines, which went into effect on January 1, 2024.

As finalized in the 2024 MA final rule, CMS specifically prohibits the denial of coverage of items or services based on internal or proprietary clinical criteria for benefits covered by traditional Medicare, for which the benefit is "fully established." This was directly responsive to AMRPA's and many others' concerns about the proliferation of proprietary guidelines being used to deny access to IRF care. Traditional Medicare standards for determining the medical necessity of admissions to inpatient rehabilitation hospitals are extraordinarily detailed in both statute and regulation. The IRF coverage criteria, specified in 42 C.F.R § 412.622(c), constitute fully established coverage criteria under the definition advanced by CMS. In fact, the regulations finalized with the 2024 MA final rule explicitly affirm that MA plans must abide by the Traditional Medicare coverage criteria specific to Inpatient Rehabilitation Facilities.[9]

Despite this clear statement from the agency, our members continue to report that MA plans commonly rely on internal coverage criteria – frequently those developed by Milliman (now MCG) or InterQual – to deny authorization and coverage of IRF admissions. These reports have continued well into 2024, with little reported change in frequency, after the new CMS prohibitions on such criteria went into effect. In many cases, members have reported that plans appear to use these criteria to suggest that certain diagnoses categorically do not qualify for acute inpatient rehabilitation services, which is directly in conflict with the Medicare IRF coverage criteria. IRF admission decisions, by Medicare's mandate, must be driven on an individual basis, including an individualized assessment of each potential IRF patient's needs and prospective outlook in response to treatment. Patients who are appropriate for IRF care have conditions that

[6] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22,120 (April 12, 2023).

[7] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024 – Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 89 Fed. Reg. 30,448 (April 23, 2024).

[8] 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 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, 89 Fed. Reg. 8,758 (Feb. 2, 2024).

[9] 42 C.F.R. § 422.101(b)(2): "[Each MA organization must comply with] General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, ***and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3).***" (emphasis added)

are serious enough to require intensive, interdisciplinary treatment, in a hospital setting, with significant medical management and oversight, regardless of their diagnosis. There is no Medicare IRF coverage criterion that suggests that certain diagnoses would not be considered reasonable and necessary for Medicare coverage, if the patient is evaluated as meeting the requirements for physician supervision and an intensive rehabilitation therapy program.

The fact that MA plans not only continue to rely on now-prohibited internal criteria to make medical necessity decisions for IRF care, but that these guidelines clearly levy additional barriers to care that would be covered in Traditional Medicare, is highly concerning, and flies in the face of CMS' intended outcome of these new rules. We believe it is critical that the agency prioritize enforcement of this rule to ensure that MA beneficiaries are not denied care to which they are entitled under the Medicare program.

AMRPA strongly supports this proposal, both with regards to the industry-wide annual submission and the targeted audit protocols, and we urge CMS to begin collecting and reviewing this information from MA organizations as quickly as possible. While we are pleased that the agency is recognizing the need for more stringent oversight in this area, we are concerned that this ICR indicates the agency may not have sufficient visibility into plans' use of internal coverage criteria currently, and thus that the audits being conducted in calendar year 2024 may not meaningfully address current plan compliance with Medicare regulations. We hope that the finalization of this proposal indicates increased emphasis on the use of internal criteria in future audits, and that the ongoing audits conducted in this year will nevertheless include compliance with these requirements as a key component of the agency's review.

III. Recommendations for Specific Data Elements Included in CMS' Proposal

Justification for "Not Fully Established"

As previously noted, AMRPA members frequently report that MA organizations deny IRF admissions while citing internal or proprietary coverage guidelines, without providing a justification for the use of such guidelines under Medicare regulations. AMRPA firmly believes that the coverage criteria for inpatient rehabilitation is fully established under traditional Medicare regulations, and thus that no internal guidelines should be allowed when determining MA beneficiaries' access to this benefit. However, if plans continue to insist on the use of such guidelines, it is critical that CMS' audits establish not only that these criteria are used, but identify the plans' justification for their use, so that the agency can fully evaluate plans' compliance (or lack thereof) with current program requirements. Therefore, we encourage CMS to strengthen and expand on the proposed requirement for substantive statements and reasoning for the use of these guidelines in the *Audit Protocol*, *Standardized Formatting*, and *Supplemental Questions* documents.

Universe Table 1, Element E in the *Audit Protocol* requires a Yes/No response if the organization determined a given benefit is not "fully established" due to a lack of applicable Medicare rules, and the following elements require the organization then cite all Medicare rules and coverage determinations that are applicable. Similarly, a determination by an MA

organization that a given item or service is not fully established because there is a need to "interpret or supplement" the current coverage criteria (Element I) should require substantive justification to support the organization's determination. Thus, in the *Standardized Formatting* document, Part 2 (*Analysis for Internal Coverage Criteria*), we recommend that CMS add an additional column requiring plans to explain why they have determined that specific language in Column C requires additional interpretation (i.e., why the language in the Medicare rule is not sufficiently clear on its face to reflect a fully established benefit). We believe this is important to include in addition to Column E in the same document, which requires plans to provide a statement detailing how each specific interpreted criterion provides clinical benefits that are highly likely to outweigh any clinical harms.

We also recognize that some of this justification could be included in Part 4 of the *Standardized Formatting* document (*Summary of Evidence/Rationale for Criteria*), but we believe this should be expanded and clarified to be required for each criterion where a plan determines internal guidelines are needed. Furthermore, we note that this Part 4 is currently detailed in the *Instructions* document as "Organizations ***may enter*** their summary of evidence and rationale for criteria in this section…"; we believe CMS intended this section to be required for each criteria used and thus the *Instructions* language should be revised.

Public Accessibility of Internal Criteria

We appreciate that CMS is emphasizing data collection regarding the public accessibility of plans' internal criteria. In our members' experience, some plans may technically make internal criteria publicly available, but it is frequently exceedingly difficult to determine where and how to access such criteria. As CMS is proposing to require that all plans submit a direct website link where specific internal coverage criteria can be found as part of the annual submission, we recommend that CMS publicize those links so that all stakeholders can easily determine what criteria may be applicable to given items and services.

Furthermore, we appreciate that for the audited plans, the *Supplemental Questions* specifically requires plans to detail the steps beneficiaries and providers must take to access internal criteria; we have received consistent reports that plans may obscure criteria behind maze-like website structures, require users to create accounts, and provide detailed information in order to access these criteria. While it may be outside the scope of this ICR, we encourage CMS to further specify the standards under which plans must make these criteria publicly accessible, and consider requiring clear, consumer-friendly specifications such as those incorporated in CMS' Hospital Price Transparency regulations (e.g., have links to criteria prominently displayed on plans' websites, be accessible without having to register or establish a user account or password, etc.).

Impact Analysis

We appreciate CMS' inclusion of the *Impact Analysis* requirement for those plans found to be out of compliance with the standards laid out in regulation and clarified in this ICR. We believe this to be an important tool in allowing CMS (and the public, as we believe these analyses should

be made public as part of CMS' response to non-compliance) to gauge the true burden of plan practices on beneficiaries. To further that aim, we recommend that CMS include a new element(s) requiring plans to calculate the total dollar amount of services that were denied (both initial determinations and reconsideration requests) resulting from the use of inappropriate criteria and/or guidelines. This should include the cost of denied services either that the patient would have been required to pay out of pocket or reimbursement that the provider would have received had the plan approved the request. Estimating the fiscal impact of plans' inappropriate denials, in addition to the absolute number of inappropriate denials, should better inform the agency's response and could be considered when determining any penalties assessed on plans as a result of their non-compliance with Medicare rules.

Furthermore, the true impact of inappropriate denials has ripple effects beyond the financial cost of replacing denied services. For example, following a denial of an IRF admission, patients may be diverted to lower cost settings, where they may be unable to receive the intensive level of care required by their condition. Not only does this frequently impacts the level of function and independence that a beneficiary may be able to regain, it can also result in overutilization of follow-on services later on, such as readmissions to an acute care hospital or longer-term use of nursing or outpatient care, which could have been avoided had the patient received appropriate, medically necessary care in the first place. We strongly encourage CMS to take a broad view of the "impact" when services are inappropriately denied and, accordingly, to require that plans incorporate these additional impacts into their mandated analyses when the agency identifies non-compliance with existing rules.

CMS List of Targeted Services

We recognize that resource limitations in CMS' audit department and the vast array of items and services covered by Medicare likely necessitate the "targeted services" approach that the agency proposes for the MA organization audit protocol. We believe that 20 items and services is a reasonable number to focus on and expect that this limited universe will allow CMS audit staff to conduct an appropriately stringent review of MA plans' compliance with the internal coverage criteria rules specific to these items and services.

However, we note that the proposed ICR does not include any discussion of how CMS proposes to identify the list of targeted services. We believe it is important to ensure that the targeted services reflect those services that have been identified as highly likely to face inappropriate denials by MA plans. While in future years, the service level data on organization determinations reported by plans (if finalized as proposed by CMS[10]) should help inform CMS' decision-making as to those services with especially high levels of denials, we believe that IRF admissions should certainly be included in the first round and likely future rounds of annual audits.

[10] AMRPA strongly supports the finalization of CMS' other recent proposed ICR in this area, *Information Collection Request on Service Level Data Collection for Initial Determinations and Appeals* (CMS-10905). AMRPA's full comments on that proposal can be found here: https://amrpa.org/wp-content/uploads/2024/10/AMRPA-Comments-on-CMS-ICR-Service-Level-Data-Collection_FINAL.pdf.

In addition to the extensive reports about problematic MA practices in this area submitted by AMRPA and others, other federal oversight bodies have also identified concerns with MA beneficiaries' access to IRF services and plan behavior regarding authorization for such admissions.[11] Given these findings and CMS' own recognition that special attention is needed to MA plan administration of post-acute care benefits (as evidenced by the specific references incorporated in regulation and in the preamble to the 2024 MA final rule), we believe it is appropriate to prioritize IRF and other post-acute care services in CMS' targeted audits going forward.

IV. Public Reporting of Newly Collected Data

As we have stated in prior comments, including in our recent response to CMS' ICR on *Service Level Data Collection*, AMRPA wishes to reiterate the importance of making relevant MA data *publicly available and easily accessible* for all stakeholders. CMS should consider all opportunities to report the data collected from payers in an easily searchable, consistent, and coherent manner. At a minimum, CMS should make the data included in the annual submission under this ICR publicly reported; as noted throughout the proposal, plans are already required to make their use of proprietary guidelines and internal coverage criteria publicly accessible, but thus far this has been, at best, implemented in a fragmented and difficult to navigate manner. We also believe that the *Impact Analyses* provided by plans found to be out of compliance with Medicare rules should be made public. Medicare Advantage beneficiaries, providers, and other stakeholders should be able to access this information quickly and easily in order to better evaluate what can be expected from the health plan choices made available.

Furthermore, the data should be aggregated at a central, CMS-supported, consumer-facing site, similar to the way consumers can use Care Compare in making decisions about health care providers. The information provided under this proposed ICR should not include any identifying data elements, and thus CMS should be able to provide this data and allow members of the public to review plans' own performance and usage of internal criteria. This would support beneficiaries' ability to consider the full spectrum of information when making decisions regarding their health plan options. Additionally, CMS should consider ways to incorporate this data into quality reporting programs, such as MA Organization Star Ratings, to ensure that payers are held accountable for their performance.

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AMRPA appreciates the opportunity to comment on this ICR and we look forward to the finalized proposal. AMRPA and our members remain committed to working with CMS to ensure that the Medicare Advantage program and all payers maintain robust and appropriate access to

[11] *See, e.g.,* HHS OIG, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns about Beneficiary Access to Medically Necessary Care (Apr. 2022) (https://oig.hhs.gov/oei/reports/OEI09-18-00260.pdf) (finding that IRF services are among the "most prominent" of the service types that MA plans denied despite meeting Medicare coverage rules); Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy 298 (March 2017) (finding that MA beneficiaries have one-third the access to IRF care than Traditional Medicare beneficiaries).

medically necessary covered benefits for enrollees. If you have any questions regarding our comments, please contact Joe Nahra, AMRPA Director of Government Relations & Regulatory Policy, at (202) 207-1123 or by email at jnahra@amrpa.org.

Sincerely,

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