November 12, 2024

The Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Division of Regulations Development
Room C4-26-05
Attn: CMS-10913
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments submitted electronically

Dear Administrator Brooks-LaSure:

LeadingAge has been vocal on the need for enforcing Medicare Advantage (MA) plan compliance with both Medicare and MA regulations and has committed to assisting in this endeavor by reporting non-compliance trends as reported by our skilled nursing facility (SNF) and home health agency (HHA) members. Therefore, we are grateful for the opportunity to offer our support for but also provide further input into CMS' Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request (CMS-10913).

Overall, we appreciate CMS's proposal to update both the data to be collected from all MA and Special Needs Plans (SNPs) and the MA/SNP audit protocol to include MA plan internal coverage criteria (ICC) to ensure compliance with the CY2024 MA policy and technical rules (CMS-4201-F). However, if the goal is to assist CMS with its enforcement and oversight of plan compliance with regulations related to ICC, then we recommend the following revisions to what is proposed.

Annual Data Request

First, the annual data request on ICC basically calls for each plan to submit a catalog of items and services for which they apply ICC, the plans and geographies in which these ICC are used, and a link to where the criteria and guidelines can be found on the plan's website. This will provide CMS with the volume of ICC currently in use and allow CMS to examine trends across plans to see if particular items or services are more likely to have ICC. What it does not tell us is whether the plans are in compliance. If plans are following the regulations, they can only have an ICC when: 1) the Medicare regulations do not fully establish criteria for a service; 2) when there is current evidence and/or clinical literature to support the ICC; 3) the clinical benefits of the ICC are likely to outweigh any clinical harms to the beneficiary; and 4) where the plan's utilization management (UM) committee has annually reviewed and

approved the ICC. Therefore, the plans already have this information or should be tracking this information. Therefore, to effectively enforce the regulations related to ICC we recommend all plans as part of this Utilization Management Data Request should have to submit not only the data currently proposed but CMS should add, at a minimum, two additional data points: 1) the current evidence and/or clinical literature upon which the plan relied and established each ICC; and 2) an indication of whether the ICC was reviewed and approved by their UM committee or date of such approval. A requirement to report this data to CMS will increase the likelihood that the plans ensure they have this information and have taken the necessary actions. Where this information is not reported by a plan, it would serve as a red flag that further examination of an ICC is warranted. We believe this more robust data submission will aid CMS in more accurately identifying which plans should be selected for an audit of their UM practices related to ICC.

In addition, it is important to note these ICC practices not only apply to prior authorization determinations but also concurrent reviews or plan determinations about when to terminate coverage. In SNF and HHA, we have seen MA/SNP enrollees have their coverage end because they "fail to make progress" or "can ambulate more than 100 feet" or they no longer need rehabilitation services but still need other skilled services such as Intravenous (IV) treatment prescribed by a physician for a specific duration. IV therapy is a covered skilled service under traditional Medicare (409.33 (b)) and yet our members have reported numerous examples of plans issuing last day of coverage notices to individuals in a SNF that are in the middle of a prescribed IV therapy regimen. These onerous denials lead to appeals that are time consuming and should not be necessary, and they place undue stress on the person trying to recover and their families. It is not clear if the plans in these cases are blatantly flouting the regulations or if they are just ignorant of the regulations across the various types of post-acute care services. Regardless, the MA program promises Medicare beneficiaries equitable access to Medicare Part A & B services; this expectation is affirmed in the 2024 MA final rule that explicitly states that MA plans must abide by the Traditional Medicare coverage criteria specific to Skilled Nursing Facility Care and Home Health Services.[1] For these reasons, we ask CMS to pay close attention to plan denials for SNF services related to IV treatments as it conducts its audits. Each of the denials noted above conflicts with 42 CFR part 409 subparts D and E related to SNF and HHA services. Therefore, we hope CMS will look beyond just how these ICC are used for initial service determinations but also decisions about whether care should continue. We've had reports of plans terminating care early even though it is clearly defined as skilled care under traditional Medicare regulations.

<u>Audit Protocol and Data Request for Medicare Part C Utilization Management</u>

We strongly support the various elements proposed to be submitted by the selected plans as part of the audit process. However, we are interested in learning more about what criteria CMS will use to select a subset of sponsoring organizations that will be subject to the audits of these ICC and what factors will determine which services and items CMS will examine as part of this process. For example, will sponsoring organizations be chosen at random for a global audit that includes an examination of the ICC? Or will CMS select certain sponsoring organizations based upon a review of the Medicare Part C utilization management Annual Data Request submissions, or will it randomly select organizations to be audited solely on their ICC?

We also 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 listed 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.

It is highly concerning that MA plans continue to construct barriers to their enrollees receiving medically necessary post-acute care such as SNF and HHA services that are covered under traditional Medicare by employing their own ICC. LeadingAge urges CMS to quickly implement this annual data request related to ICC for all MA/SNP plans beginning January 1, 2025, along with the corresponding audit protocol and data request for selected plans. Understanding how and when plans are utilizing ICC and ensuring compliance with the CY2024 MA rules (CMS-4201-F) are critical to ensuring beneficiaries are not wrongfully being denied access to traditional Medicare services when they are medically necessary.

Public Accessibility of Internal Coverage Criteria

We appreciate that CMS is emphasizing data collection regarding the public accessibility of plans’ ICC. In our members’ experience, some plans may be technically making ICC publicly available, but it is frequently and exceedingly difficult to determine where and how to access these criteria. As CMS is proposing to require that all plans submit a direct website link where specific ICC 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 ICC; 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 data request, 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 a valuable 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. However, we would encourage CMS to consider also requiring plans to calculate the total dollar amount of services that were denied (both initial determinations and reconsideration requests) resulting from their inappropriate use of internal 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 providers 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 utilized to determine any proportional penalties assessed on plans as a result of their non-compliance with Medicare 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 ICC rules specific to these items and services.

However, we note that the proposal does not include any discussion of how CMS will 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[2]) should help inform CMS' decision-making as to those services with especially high levels of denials.

In addition, recent studies of MA plan practices related to post-acute care coverage determinations suggest CMS should prioritize review of post-acute care service coverage determinations by MA plans. The recent Senate Homeland Security Committee's Permanent Subcommittee on Investigations report, "Refusal of Recovery: How Medicare Advantage Insurers Have Denied Patients Access to Post-acute Care," highlights the trend that plans are denying post-acute care at higher levels than overall prior authorizations between 2019 and 2022. Similarly, the Office of the Inspector General also raised

concerns in April 2022 about inappropriate service denials by plans.[3] LeadingAge along with its post-acute care association partners have been collecting data on prior authorizations and re-authorization requests in 2024, as part of a MA Prior Authorization Data Collection Initiative. Our data thus far suggests that plan behaviors have changed little related to SNF and HHA services since the implementation of the CY2024 MA rule. 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 SNF, home health care and other post-acute care services in CMS' targeted audits going forward.

Public Reporting of Newly Collected Data

As we stated in our prior comments, including in our recent response to CMS-10905 on *Service Level Data Collection*, LeadingAge again encourages CMS to publish relevant MA data from these data requests to inform stakeholders, including consumers, regarding these practices. CMS should pursue 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 annual data request publicly reported; as noted throughout the proposal, plans are already required to make their use of proprietary guidelines and ICC publicly accessible, but publishing this somewhere on their websites does not make it easy for consumers to find or use to compare their plan options. In addition, for plans found to be non-compliant with the Medicare regulations related to ICC, CMS should make these findings public as they do with the issuance of other audit findings and civil monetary penalties. MA beneficiaries, providers, and other stakeholders should be able to access this information quickly and easily to better assess and compare the available health plan options.

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 plans are required to submit under this proposal should not include any personally identifiable information, and thus CMS should be able to provide this data and allow members of the public to review plans' own performance and usage of ICC. 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.

Thank you for the opportunity to share some of our ideas for how the proposed data collection related to plans' use of ICC and the corresponding audits could be enhanced to achieve its goals to ensure regulatory compliance. These data are critical for transparency as more and more beneficiaries shift to the MA program to ensure they have access to the Medicare A and B services to which they are entitled. As always, please reach out to me with any questions at nfallon@leadingage.org.

Sincerely,

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LeadingAge

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LeadingAge represents more than 5,400 nonprofit and mission-driven aging services providers and other organizations that touch millions of lives every day. Alongside our members and 36 partners in 41 states, we use applied research, advocacy, education, and community-building to make America a better place to grow old. Our membership encompasses the continuum of services for people as they age, including those with disabilities. We bring together the most inventive minds in the field to lead and innovate solutions that support older adults wherever they call home. For more information visit leadingage.org.

Endnotes

[1] 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)

[2] LeadingAge strongly supports the finalization of CMS' other recent proposed data collection in this area, *Information Collection Request on Service Level Data Collection for Initial Determinations and Appeals* (CMS-10905). LeadingAge's full comments on that proposal can be found here: https://leadingage.org/wp-content/uploads/2024/10/CMS10905-Service-Level-Initial-Determinations-Data-Collection-FINAL-100724.pdf.

[3] *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)