
November 29, 2023

Meena Seshamani, Deputy Administrator and Director
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: Recommendations for sub-regulatory guidance related to CMS-4201

Sent electronically.

Dear Deputy Administrator and Director Seshamani:

On behalf of the undersigned post-acute care (PAC) and related organizations, who represent the views of beneficiaries, skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals and home health agencies, we want to thank CMS for their efforts to address and reform some of the issues we each identified with the current Medicare Advantage program and MA plan practices, as part of the Calendar Year 2024 Medicare Advantage (MA) Policy and Technical Rule (CMS-4201, referred to throughout this letter as the “final rule”).

Together, we have identified the key areas of the final rule that we believe warrant sub-regulatory guidance to clarify how the final rule should be implemented related to PAC settings. More detailed guidance will ensure improved access to care for Medicare beneficiaries and clarity for providers. At present, our provider members are hearing from MA plans that they don’t believe they need to do anything different based upon the final rule. This would suggest the intent of the rule is not yet clear regarding plan compliance obligations. Below, we outline the implementation issues we anticipate will be encountered with the final rule implementation. In addition, we offer specific recommendations and PAC examples on these issues to underscore the rule’s intent in these areas.

Our recommendations broadly ask CMS to include the following clarifications in sub-regulatory guidance to ensure the intent of the final rule changes are achieved for beneficiaries:

- MA plans should be required to follow Medicare regulations, including CMS transmittals, CMS provider manuals, the Jimmo v. Sebelius settlement policy, and PAC assessments, in addition to other items already identified in the final rule.
- CMS should provide examples and clarification of the limited circumstances in which a plan can override a physician’s medical necessity determination.
- CMS should identify the specific actions MA plans must take and circumstances when they employ internal coverage criteria, including how that information is to be publicly disclosed and the evidence and tools the plan used to develop their criteria. We suggest this should align with the rules the Medicare Administrative Contractors follow in these situations.

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- CMS should clarify the specific elements that must be contained in denial notices such as person-specific details for why a service is denied or terminated including identifying what information is lacking, any internal criteria used to make the decision, the specific regulatory requirement that isn't met, identifying the health professional who reviewed the request and citing specific denial codes.
 - CMS should prohibit use of algorithms or artificial intelligence from use in coverage denials and limit other uses of these tools until a systematic review of their use can be completed.
 - CMS should clarify the application of the term "course of treatment" in PAC settings such as a prior authorization for a course of treatment follows the beneficiary across care settings, covers an entire PAC stay based upon an in-person PAC assessment of the beneficiary and may require services from more than one PAC provider during the "course of treatment." This includes changes in condition that extend the need for services.

Further details of each recommendation are provided below.

Medicare Parts A & B Coverage Determinations

Section 422.101 of the final rule requires plans to "provide coverage of ... all services that are covered by Part A and Part B of Medicare..." The final rule detailed additional items that MA plans must follow, including national and local coverage determinations, general coverage and benefit conditions included in Traditional Medicare laws including following payment criteria, services, and procedures. The rule specifically notes that these provisions include payment of Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs), and Inpatient Rehabilitation Facilities (IRFs). Although CMS modified 42 CFR §412.3 related to inpatient admissions under Medicare Part A, which covers services provided in long-term care hospitals (LTCHs), CMS did not include LTCHs in its preamble. Therefore, it is not clear if LTCHs were intentionally excluded or if this omission should be remedied in sub-regulatory guidance.

Recommendation: For post-acute care services, we would like the sub-regulatory guidance to note that the intent of this section of the final rule is to emphasize that MA plans must follow the items listed below as they are integral aspects of the implementation of Medicare regulations, payment, and coverage:

- **CMS transmittals.** CMS uses transmittals to communicate new or changed policies or procedures that it will incorporate into the CMS Online Manual System, which is used to administer CMS programs. CMS has indicated in the final rule that MA plans, like other contractors, should be expected to follow traditional Medicare policies. One example where Medicare policy is not being followed is with regard to Publication 100-20, Transmittal 2278 regarding SNF interrupted stays. CMS defines an interrupted SNF stay as one in which a patient in a covered Part A SNF stay is discharged from the SNF for no more than three consecutive calendar days and subsequently readmitted to the *same* SNF during the interruption window. According to the transmittal, this is considered a continuation of the same SNF stay and is not treated as a new admission. At present, MA plans in Connecticut are not following the policy established by this transmittal and are requiring a new prior authorization for a beneficiary who is on an interrupted stay. If the person returns to the SNF without the "repeat" prior authorization, the plan will not cover *any* of the costs of the SNF care received. Under Traditional Medicare, the beneficiary would return to the SNF without an interruption in coverage/payment as it is treated as a continued stay. There is a similar policy in the IRF PPS. This practice by the plans does not advantage the beneficiaries as it is more restrictive than Medicare coverage policies and results in either beneficiaries or the SNF covering the costs of

the care provided, even though it clearly falls under the plans' obligation. Therefore, we believe plans should follow such transmittals in complying with coverage for Medicare Parts A and B services.

- **CMS manuals for each provider type.** The new regulatory language at §422.101(b)(2) removes reference to sub-regulatory guidance, including the Manuals, as authority that MA plans must rely upon. While the preamble to the final rule states that CMS expects MA plans to consult such materials, we urge CMS to make it explicitly clear that MA plans are bound by them. This clarity could be included within an update to the Medicare Managed Care Manual citing how plans handle each provider type including cross referencing provider-specific Medicare manuals.
- ***Jimmo v. Sebelius* settlement.** The *Jimmo v. Sebelius* settlement agreement states that a beneficiary's lack of potential for improvement or restoration cannot be the sole reason for denying skilled care under Medicare. This same intent is supported in 42 CFR§409.32: *"The restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities."* Regrettably, SNFs and HHAs have witnessed plans increasingly denying care for this cited reason and not abiding by the terms of the settlement. SNF and HHAs providers are seeing MA plans make determinations based exclusively on a patient's therapy notes without consideration of their need for medical management; and deny or discontinue care due to lack of progress in therapy, which is in direct violation of the [Jimmo v. Sebelius settlement/CMS policy](#). The Center for Medicare Advocacy, which brought the Jimmo lawsuit along with Vermont Legal Aid, continues to counsel Medicare beneficiaries who are improperly denied, or prematurely terminated from, services using an inappropriate improvement standard. In the Center's experience, this barrier to care is even greater for MA enrollees.
- **PAC assessments.** PAC provider Medicare regulations require each PAC setting to conduct site-specific, in-person assessments on every Medicare beneficiary they serve and often all residents/customers. Assessments are required again when there is a change in the person's condition. These assessment tools include: the Skilled Nursing Facility (SNF) OBRA and SNF PPS Minimum Data Set (MDS), [Outcome and Assessment Information Set \(OASIS- E\) for Home Health Care](#), [Patient Assessment Instrument \(PAI\) for Inpatient Rehabilitation Facility \(IRF\)](#) and the [Long-Term Care Hospital \(LTCH\) Continuity Assessment Record Evaluation \(CARE\)](#). These assessments are used to evaluate quality and determine the level of payment within the Medicare program for the services provided. In contrast, MA plans exclusively make coverage determinations without seeing the patient ("paper reviews" only) and as such, are not fully aware of any of the patient's limitations. Whereas, the PAC assessments are standardized, evidence-based and conducted by in-person health care professionals with expertise in the care to be provided via objective, observed measurement. MA plans increasingly use algorithms/AI tools to challenge these PAC provider assessments – even in settings where the plan requires the provider assessment (e.g. in home health, MA plans require the completion of OASIS-E). Specifically, providers across PAC settings are reporting MA plans disregarding these CMS-required assessments with regard to: 1) coverage denials and discontinuations, including failing to recognize changes in condition that warrant additional Medicare-covered services, and 2) requiring providers, under the threat of not being paid, to downgrade the patient's assessed

level of care.

EXAMPLE: When an MDS assessment is completed in a SNF, it informs not only the care plan but also the payment level required for the service under traditional Medicare. MA plans are not beholden to this payment structure although many pay SNFs a percentage of the Medicare FFS structure. However, plans are directing these SNF providers to ignore the documented patient characteristics items supporting published patient classification criteria derived from these assessments, even though the patient record indicates the presence of a condition or care needs that meet the criteria for a higher reimbursed classification. Additionally, MA plans are increasingly pressuring SNFs to down code the MDS level in violation of federal MDS documentation and coding requirements. Plans are telling SNFs that they will not pay for the level of care identified by the in-person assessment and that the SNF should only submit a claim for reimbursement at a lower level of care it designates. This is especially problematic in cases where the plan pays using the Medicare Part A case-mix methodology. In other words, the plans are disregarding the outcome of Medicare-required assessments and forcing providers to accept a lower payment for these services or receive no payment at all. Requiring providers to submit inaccurate medical necessity information so plans can reduce the provider payment or threatening the provider with non-payment if the provider files a claim based on assessed levels constitutes fraud and should not be tolerated. Even in home health where plans do require OASIS-E assessments, we still see de facto “downgrading” of level of care by virtue of plans only authorizing a small number of visits despite documentation in the plan of care and the assessment.

Recommendation: Therefore, as CMS clarifies what Medicare regulatory requirements plans must comply with, we recommend that PAC assessments informed by the patient’s medical record, including assessments conducted when there is a change in condition, be one of these required items (where it is not already required). Given that CMS utilizes these tools to judge payment and quality within the Traditional Medicare program, we believe the MA/Special Needs Plans (SNP) plans should be required to abide by the assessed level of care much like a physician’s recommendations for care, and as is the case in Traditional Medicare. In addition, MA plans should not be permitted to use algorithmic/AI tools, which are based upon generalized experiences, to override the CMS-required PAC assessments that are based upon a health care provider observing the patient.

We also would like CMS to clarify that plans are prohibited from requiring providers to downgrade the level of care assessments and providers should be paid at assessed levels. Plans are provided with this information by treating clinicians and should use this information in their coverage decisions.

Plans should be required to conduct an in-person assessment of the enrollee if denying care, shortening the course of treatment, or terminating care and that determination contradicts evidence-based, required PAC assessments and onsite health care professional advice.

Overriding a Physician’s Determination of Medical Necessity

We believe it is imperative that the regulation and accompanying sub-regulatory guidance curtail instances where MA plans use rationales for denying care that run counter to a treating physician’s assessment. In the context of IRF admissions, for example, IRF providers report that plans deny an IRF authorization on the grounds that the patient “could be treated in a less intensive setting” or “would not benefit from an intensive therapy program,” among similar rationales. These denials are issued despite the fact that the patients’ treating physician explicitly determined that a patient *did* in fact require hospital-level care and that the patient would benefit from the specialized services offered by IRF providers. These plan behaviors also run into direct conflict with CMS’ prior assertions that such rationales were impermissible grounds for which to deny an IRF admission.

The issues with this type of plan behavior – and the need for effective program rules in this area – have been illustrated in instances where patients and the IRFs have appealed these types of denials. In many cases, a patient will begin their care in an IRF while their appeal with the plan is pending. In those scenarios, the patient’s excellent functional recovery in the IRF makes clear that the patient both needed and benefitted from the IRF referral – providing a “real time” rebuttal of the plan’s initial denial.

Even though these types of rationales violate plan rules and run counter to the patients’ clinical needs, plans nonetheless continue to issue these types of inappropriate denials. It is therefore imperative that CMS issues sub-regulatory guidance that makes clear that the physician’s referral should be given deference and engages in enhanced oversight regarding plan authorizations and rationales.

When Internal Coverage Criteria are Permissible

The final rule establishes 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.”* (§422.101(b)(6))

We recommend CMS make the following clarifications in sub-regulatory guidance:

- 1) Require plans to follow similar rules or criteria used by the Medicare Administrative Contractors (MACs) when establishing the need for “internal coverage criteria” to ensure consistency.
- 2) Provide specific examples of circumstances when it is permissible or impermissible to develop and utilize internal coverage criteria. As the Office of Inspector General pointed out, it would be beneficial for CMS to define what it considers “no more restrictive than” or “contradictory to” Medicare coverage rules. For example, a guideline could say, “it is not permissible to have internal coverage criteria that deny care due to an inability to make progress in therapy when skilled care services are still required.”
- 3) Outline what a plan must demonstrate under 42 CFR §422.101 (b)(6)(i)(A) to show that the *“clinical benefits ...are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.”* How must a plan document this information? When will it need to be submitted to CMS by the plan? And how (through what process) can a beneficiary or provider challenge the plan’s position?

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- 4) Require MA organizations to meet the “publicly accessible” requirement by publishing these internal coverage criteria on their website in a portion of their website accessible to providers and beneficiaries (with no login required) and labeled as “internal coverage criteria.” This information should be posted at the beginning of the plan year and beneficiaries notified at least 30 days in advance of the effective date of any changes made to the policy. These internal coverage criteria should also be made available upon request by the beneficiary, their family, and/or a provider involved in their care through the plan’s customer service line. The available information must include the guidelines used in the internal coverage criteria provided in an easily digestible way so the beneficiary can compare their facts to the established criteria. This is a similar process that Medicare Administrative Contractors (MACs) must follow. In addition, clarify how the “publicly accessible” requirement applies to algorithms or AI-based criteria.
 - 5) Specify that the plan must demonstrate how its internal coverage criteria meet the terms of “widely-used treatment guidelines,” including citing the clinical literature or research used in developing the internal coverage criteria and confirm how the literature or research meets the requirement and addresses the specific coverage question. Internal coverage criteria should be prohibited from being based upon an algorithm or AI until a review of these tools can be completed and the source data divulged.
 - 6) Clarify that algorithms or artificial intelligence tools based upon unpublished data or research and/or derived exclusively from proprietary analysis do not meet the “widely-used treatment guidelines” definition. Therefore, while they may be used to help inform internal coverage guidelines or coverage decisions, internal coverage guidelines may not exclusively be based on artificial intelligence tools. Coverage decisions applying such internal coverage guidelines must be made based on the assessment of the individual and their need for post-acute care.

Detailed Denial Notices

We support the language in the final rule regarding the level of detail that must be contained in coverage denial notices. Particularly, the final rule states, “... MA organizations must give enrollees written notice of a denial and the notice must state the specific reasons for the denial. We clarify here that if an MA organization denies care based on internal criteria, that criteria must be clearly stated in the denial notice, just as other applicable Medicare coverage criteria must be stated under §422.568(e)(2), when used as the basis for a denial of coverage. Communicating all necessary information needed for the enrollee or provider to effectively appeal the decision, including the evidence used to support the internal coverage policy when applicable, is one of the purposes of the denial notice. The standardized Integrated Denial Notice is properly completed when it includes a specific and detailed explanation of why the medical services, items or Part B drugs were denied, including a description of the applicable coverage rule or applicable plan policy (for example, Evidence of Coverage provision) upon which the action was based, and a specific explanation about what information is needed to approve coverage must be included, if applicable.” However, when services are denied, many MA plans are using what appear to be form letters offering little to no detail about the cause for denial.

Example: One SNF provider reports that the most frequent denial notice received by the beneficiaries they serve states, “Based on Medicare guidelines and the information we have about your condition, you don’t meet all the requirements. The requirements are: (1) you need skilled nursing care or rehabilitation services every day AND (2) the services are reasonable and necessary for the treatment of your illness. You can receive the care you need in another setting, such as home, a long-term care facility, or other outpatient setting.” Similarly vague notices are often provided with denials of admission

to inpatient rehabilitation hospitals as well. These notices do not say which requirement was not met by the beneficiaries' records and circumstances nor what information is currently missing that would substantiate the need for PAC care. Therefore, we would not consider this meeting the requirement of detailed as it is generic language that does not describe the individualized circumstances of the beneficiary. We know that some plans are wrongfully denying care and yet based upon the above denial notice language from this MA plan, there is evidence the MA plans believe they are complying with Medicare coverage criteria. For this reason, we are not confident that plan behavior will change without further education and/or consequence. In addition, the rule notes that when denials are made, they are required by rule to be reviewed by a health professional with relevant experience. Given our collective experience receiving denials across the continuum of post-acute services, plans' assurances that beneficiaries can receive services in a different setting also ring false and need to be closely scrutinized by CMS.

Recommendations: We encourage CMS to clarify that the MA plan denial notices must specify what evidence is lacking to approve or continue the care (e.g. no physician order, diagnosis missing, etc.), the process for submitting the additional information, any internal criteria the plan may have used to make the determination, and the rationale for not covering the service, including any direct references to the regulations specific to that provider type. We also support a type of detailed template for these communications, which may aid MA plans in complying and ensuring that the communications are easy for beneficiaries and their families to understand while providing a detailed, patient-specific rationale(s) for the denial. Medicare Administrative Contractors already utilize an extensive list of setting-specific "denial reason codes" for Traditional Medicare admissions through CMS' esMD system – at the least, MA plans should be able to provide as much information as is provided in these codes. Additionally, as CMS seeks to implement these provisions, we ask staff to clarify that denials should include the name and qualifications of the health professional who reviewed the request as a means for ensuring this requirement is met. In some PAC settings, it is not currently being met.

Prohibitions and Limitations on Use of Algorithms and Artificial Intelligence

We have concerns about the MA plans' use of third-party tools that employ algorithms and/or artificial intelligence (AI) in determining whether care and services will be covered, the duration of the care received, and which apply a generalized need for care to an individual beneficiary's situation. However, we also recognize that algorithms and AI may hold promise for achieving certain efficiencies within health care that could speed access to care and potentially lower administrative burden. For example, they could be used to expedite prior authorizations and coverage determinations by identifying key information contained in the beneficiary's records. Currently, we know these tools are being used to erroneously deny care and contradict provider assessment findings. In addition, such tools generate generalizations vs. person-centered approach to care, which is antithetical to the current desired goal for health care delivery. There is evidence that AI is not yet sophisticated enough to self-correct when an incorrect decision is made. For these reasons, we think the use of such tools should be limited to expediting approvals of care determinations or prior authorizations but not used for coverage denials.

Since the MA rule was finalized, our providers have consistently reported plans telling them that these third-party tools are only used as "guidance" and therefore, the plans see no need to change their practices once the final rule is implemented. To the contrary, PAC providers have observed plans following these tools exclusively, even reportedly overriding their own reviewers' recommendations, to the detriment of beneficiaries. One example is the company, NaviHealth, that created an algorithmic tool used for determining the duration of care within Skilled Nursing Facilities. NaviHealth is owned by

UnitedHealth, but its tool is used by many MA plans. The tool generates a report titled, “nhPredict,” which indicates the average number of days of SNF care the person is likely to need based upon their primary diagnosis. As reported in STAT news and observed by SNF providers’ experiences with this tool, it is not used as a guide for the health plan’s coverage decisions but instead shows the specific date when Medicare coverage will be terminated by the plan. One provider shared an example where the nHPredict report, generated by a NaviHealth algorithm, noted that the length of stay in SNF for an average person similar to the beneficiary is 13.2 days. The plan or its third-party contractor (in this case NaviHealth) used this report to determine the individual’s SNF discharge date based upon this generalized, proprietary data. In this case, the algorithm indicated, the individual should be discharged after 13.2 days even though the patient still required an IV medication regimen for a prescribed additional 16 days. Under traditional Medicare FFS, the patient would have received coverage for all the SNF days that they required IV medication. But the MA plan did not cover it.

The plans do not waiver from these determinations and provider or beneficiary pleas to reconsider the coverage cutoff indicated by these reports, because an individual still requires skilled care (e.g., still on IV drug treatment) or a person has had a change in condition that warrants longer duration of care, are frequently ignored. Beneficiaries will be discharged home even when medically unstable or without appropriate family caregiver support, simply because the algorithmic report said so. Clearly, this is not what CMS intends these tools to be used for. CMS clearly indicates in the final rule that, *“MAOs must ensure that they are making medical necessity determinations based on the circumstances of the specific individual as opposed to using an algorithm or software that doesn’t account for an individual’s circumstances.”* This is not happening.

Transparency in how plans make coverage determinations is essential to ensure plans meet Medicare coverage requirements and deliver equitable access to Medicare services. Third-party tools that utilize algorithms or artificial intelligence are a black box and at best, generalize a patient experience with little consideration for specific circumstances or clinical details. There is no view into the sources of their data, whether these tools can “learn” from their mistakes and most importantly, whether they comply with Medicare regulations for coverage and payment. For these reasons, we strongly support CMS’ final rule position that, *“...use of these tools, in isolation, without compliance with requirements in this final rule at 422.101(b), (c), and 422.566 (d), is prohibited.”*

Recommendation: We urge CMS to clarify that MA plans are prohibited from using these algorithmic or AI tools in coverage determinations including prior authorizations, unless they can demonstrate that they meet the Medicare coverage requirements based on the unique beneficiary’s comprehensive assessment for post-acute care and divulge the source of the data and evidence used to create the algorithm or AI tool. We would also like clarification that the final rule applies to these tools when used in PAC settings including tools such as, NaviHealth, InterQual and MyNEXUS.

We also suggest CMS ban plans from using these tools, as a sole source, to overturn the findings of a PAC assessment, as this aligns with the final rule, which prohibits MA plans from using these tools when they do not comply with the traditional Medicare requirements. PAC assessments are required part of traditional Medicare and as noted in the final rule, *“...MA plans may not use InterQual or MCG criteria, or similar products, to change coverage or payment criteria already established under Traditional Medicare laws.”*

Also, if MA plans were following Medicare regulations, then they would not be able to use such algorithmic/AI tools, as a sole source for coverage decisions, especially for home health services, as the

regulation at 42 CFR §409.44, explicitly states, “A coverage denial is not made solely on the basis of the reviewer’s general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regard the beneficiary’s individual need for care.”

In addition, we believe CMS must be more proactive in monitoring plans’ use of AI or algorithm-driven tools. MA plans cannot be allowed to side-step oversight by claiming that these tools are mere “guidance.” Practice shows us otherwise. Absent banning the use of such tools altogether, CMS should limit the use of these tools until a systemic evaluation can be conducted on how these tools are impacting care. Specifically, we would recommend CMS, or another entity such as the Office of the Inspector General (OIG), conduct a review of a representative sampling of case files across MA plans comparing the output of algorithmic/AI tools used by the plans to actual coverage determinations including duration of coverage, number of units of service and comparing the beneficiary profile to the tool’s generalized population. Reviewing prior year case files would be one way to evaluate how religiously the tools are being followed by the plan and could analyze the accuracy of the outputs in comparison to traditional Medicare determinations. Given that we do not know what inputs are used for the algorithms and AI tools being currently used, it is difficult to know the accuracy of the information they generate and whether the inputs comply with the regulations. Therefore, CMS might also consider establishing an approval process to review such tools and their inputs to ensure the integrity of their use.

In the interim, these tools should not be used to deny coverage but limited to approving or automating prior authorization approvals.

Prior Authorizations and “Course of Treatment” in Post-Acute Care

We were thrilled to see CMS specifically explain that prior authorizations must cover a “course of treatment.” However, this term is a little less clear in its application for the post-acute care services. Dr. Meena Seshamani at the 2023 LAN Summit described this new provision as “the prior authorization moves with the person and stays with them for the duration of the treatment.” Does this mean that it follows them across care settings? The question is, how do we apply this for an individual who receives acute care in a hospital that is discharged to a PAC setting to complete their care for this episode? Typically, a prior authorization is initiated by the discharging physician at an acute care hospital before admissions to SNFs, IRFs, and LTCHs. In this case, the discharging physician has identified the optimal setting to address the beneficiary’s PAC needs and submitted the primary diagnosis from the hospitalization as part of the prior authorization request. In the case of home health care, the agency submits the request based upon the referring provider’s recommendation. What is not included at this stage is a detailed assessment of how the person’s PAC journey will be defined.

For example, while Medicare requires post-acute SNF care to be furnished related to a condition initially treated in the acute care hospital, it does not need to be the same diagnosis. Additionally, under Medicare regulations, a course of covered SNF care can be extended if a different need for skilled care arises for an emergency condition during the covered stay, even if the initial reason for the SNF stay was resolved. This information is determined within the early days of a PAC admission and throughout the stay and takes into account not only the reason for the proximal hospitalization, but also the breadth of the individual’s chronic conditions, frailty, cognition, supports, and other co-morbidities that will be considered in developing the person’s individualized plan of care in the PAC setting. CMS states in the final rule, “A course of treatment may but is not required to be part of a treatment plan.” We believe

that MA plans should be required to consider information gathered while completing the CMS-required PAC assessments which inform the PAC portion of their treatment.

Additionally, in many cases, a given patient's course of treatment for a single injury, illness, or condition may involve multiple settings of post-acute care. We believe that a prior authorization for a "course of treatment" should cross settings if medically necessary. Further, such standardization of the "course of treatment" for post-acute care would cut down on instances where plans inappropriately levy conditions on prior authorization, such as authorizing admission to an IRF only if the patient will not be subsequently transferred to a SNF or other setting besides the home. While the goal of IRF admission (and admission to other settings) is to advance the patient's health and function as much as possible, each patient's course of recovery is different and categorically "pre-denying" admission to another setting that may become necessary is a unique restriction to the MA program and goes beyond the coverage mandates of traditional Medicare.

Recommendation: We ask CMS to clarify that a "course of treatment" be defined to cover the assessed PAC services for the entire stay in the post-acute setting based on assessed need and not for arbitrary, fixed intervals of 2-, 5- or 7-day or limited visit blocks that result in time-consuming reauthorizations that often disrupt care. Plans should follow the care plan developed to meet the beneficiary's medical, psychosocial, cognitive, and behavioral needs. In addition, clarify that the duration of care be informed utilizing information from the relevant, in-person PAC assessment(s). Further, CMS is encouraged to clarify that a "course of treatment" may be modified if there is a change in condition requiring a revision to the services or the duration of service required by the beneficiary's current health.

Considerations for Future Rulemaking

We understand that CMS has already completed proposed rules for CY 2025, but we would appreciate the opportunity to further engage with staff on other areas of the MA regulations we believe CMS should take the opportunity to address, especially as MA program enrollment now tops 50% of Medicare beneficiaries. One area that we think warrants further discussion is identifying additional mechanisms to improve the reporting and tracking of MA plan non-compliance issues in a timely way. We also would like to discuss ways to improve the beneficiary complaint tracking module, process, and follow through.

We also seek to better understand how CMS is going to monitor the plans' compliance with the final rule. We believe providers could play a key role in identifying issues with implementation related to improper coverage denials or prior authorization non-compliance. We would like to assist in this process by collecting information from our members. We would be interested in discussing what information would be most useful for us to share with CMS and at what frequency. In return, we would ask that CMS publish a quarterly report that identifies prior authorization or coverage approval rates by specific post-acute care setting; percent of denials appealed by the patient and the outcomes of those appeals; and identify the qualifications of reviewers assigned to PAC authorizations. It appears that CMS is already thinking along these lines based upon its CY2025 proposed MA policy and technical rule (CMS-4205-P).

As you consider future rule revisions, we would like to work with you to establish a clear public process for providers to submit complaints when they see plans making inappropriate care denials or terminations or similar non-compliance issues. This would provide more complete data on the issues plans are encountering with interpreting and complying with rules. It has the added benefit of possibly addressing issues more quickly to speed beneficiary access to care. We believe having another channel through which to collect compliance information could improve accountability and identify non-

compliance issues that need addressing or require further rule clarification. We know that beneficiaries do not appeal all inappropriate denials or terminations. We think this fact also supports the need to look at ways in which we can expedite and simplify the appeals process for beneficiaries, including establishing a minimum time period between QIO decisions and a new MA plan denial, and permitting third parties to advocate/appeal on behalf of the beneficiary.

We renew our request to meet with Medicare Advantage staff and leadership to review these needed clarifications and discuss future rulemaking to improve the Medicare Advantage program and ensure beneficiary access to services through improved processes and provider sustainability. Please contact Nicole Fallon at LeadingAge (nfallon@leadingage.org) to schedule a meeting between the MA staff and the undersigned organizations' representatives.

Sincerely,

LeadingAge

Center for Medicare Advocacy

American Medical Rehabilitation Providers Association (AMRPA)

The National Association of Long-Term Hospitals (NALTH)

American Health Care Association (AHCA)

National Association for Home Care & Hospice (NAHC)