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November 20, 2023

Meena Seshamani, M.D. Deputy Administrator and Director Center for Medicare Centers for Medicare & Medicaid Services 7500 Security Blvd. Baltimore, MD 21244

Dear Dr. Seshamani:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners, the American Hospital Association (AHA) strongly supports the Centers for Medicare & Medicaid Services' (CMS') efforts to improve how coverage works for Medicare Advantage (MA) enrollees through the policies codified in the calendar year (CY) 2024 MA final rule. These policies, when implemented, will promote more timely access to care, ensure better alignment and coverage parity between Traditional Medicare and MA, and increase oversight of Medicare Advantage Organizations (MAOs).

<u>Recently</u>, we urged CMS to conduct rigorous oversight to monitor compliance with these policies and to ensure that appropriate action is taken in response to any violations. We expressed concerns about reports we have received from our members that certain MAOs have indicated they do not intend to make changes to their utilization management programs in response to the new rule. In other cases, it appears some plans are making changes to the terminology they use in denial letters that may be intended to circumvent recent CMS rulemaking.

Indeed, one plan recently issued <u>guidance</u> to its network providers indicating that they plan to continue using internal criteria beyond the Traditional Medicare criteria to evaluate inpatient admissions. We believe this circumvents CMS' rules regarding the use of more restrictive coverage criteria and the requirement that plans adhere to certain public accessibility and evidentiary standards. Similarly, we understand from our members that at least one other large, national MAO has reported they will continue to use Milliman Clinical Guidelines (MCG) criteria to evaluate inpatient admissions. And yet another plan has issued a policy that adopts a more stringent standard than CMS for evaluating a physician's judgement at the time of admission on whether the care was expected to extend over two midnights. **We are deeply concerned that these**



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practices will result in the maintenance of the status quo where MAOs apply their own coverage criteria that is more restrictive than Traditional Medicare proliferating the very behavior that CMS sought to address in the final rule, resulting in inappropriate denials of medically necessary care and disparities in coverage between beneficiaries in MA and those in the Traditional Medicare program.

Attached, we provide additional information regarding these potential discrepancies between these plans' guidance and the CMS rules. In response to these concerns, we urge CMS to take the following actions:

- Clarify that coverage criteria for inpatient admissions are fully established under Traditional Medicare, as set forth in § 412.3, consistent with long-standing CMS policy under Traditional Medicare.
- Clarify that the flexibility for MA plans to supplement Traditional Medicare rules with additional internal coverage criteria is <u>not applicable</u> for medical necessity reviews of inpatient admissions and level of care decisions and should only be used in certain *limited* circumstances.
- Reinforce expectations to MAOs and confirm MAO compliance with public accessibility and evidentiary standards for internal coverage criteria.
- Take swift action to correct MA plan policies that do not comply with CMS rules, including applying intermediate sanctions where appropriate.

Given the importance of these issues for beneficiaries' access to care and our hope to address these concerns prior to the effective date of the CY 2024 MA final rule, we respectfully request a meeting as soon as possible to discuss these concerns.

We appreciate your attention to the issues we have raised. And look forward to continuing this conversation. Please feel free to contact me if you have any questions or have a member of your team contact Michelle Kielty Millerick, AHA's senior associate director of health insurance coverage policy, at <u>mmillerick@aha.org</u>.

Sincerely,

/s/

Ashley Thompson Senior Vice President Public Policy Analysis and Development

Attachment A: Examples of Concerns with MAO Policies and AHA Recommendations Attachment B: Source Material Deputy Administrator and Director Seshamani November 20, 2023 Page 3 of 6

Attachment A: Examples of Concerns with MAO Policies and AHA Recommendations

The AHA has identified several substantial concerns regarding recently released MAO policies based on our understanding of the CY 2024 MA final rule. These include the application of more restrictive coverage criteria than the Traditional Medicare program, failure to meet public accessibility and certain minimum standards for use of internal criteria, and the adoption of more stringent standards than CMS uses to evaluate a physician's judgement under the two midnight benchmark. Our analysis and recommendations follow.

1. Use of More Restrictive Coverage Criteria than Traditional Medicare

The CY 2024 MA final rule states that "MA plans may not use InterQual or MCG criteria, or similar products, to change coverage or payment criteria already established under Traditional Medicare laws." It also codifies that "MA plans 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 of service is a benefit available under Traditional Medicare, *such as payment criteria for inpatient admissions at 42 CFR 412.3* [emphasis added]." Yet, despite a requirement to follow Traditional Medicare criteria, the <u>UnitedHealthcare policy</u> for reviewing inpatient admissions states that "UnitedHealthcare uses InterQual as a source of medical evidence to support medical necessity and level of care decisions."

While we understand that CMS provided flexibility for MA plans to adopt internal coverage criteria in certain, limited circumstances, these circumstances, as we understand them, are limited to cases when the applicable coverage criteria in Traditional Medicare laws (including national and local coverage determinations) are not fully established. As you know, Traditional Medicare and its auditors have been using for over 10 years the criteria at § 412.3 to determine which cases are appropriate for inpatient admissions, including the two midnight rule, the inpatient only list and the case-by-case exception criteria. It is unclear why MA plans should need to broadly apply additional, unspecified criteria in order to interpret or supplement these provisions. Doing so, in effect, changes Traditional Medicare criteria for inpatient hospital care, which is prohibited by the rule. It also is unclear and remains unaddressed in the policy referenced above how the plan's use of InterQual will address the requirement to "demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services."

CMS' rationale in the final rule for allowing plans to use internal coverage criteria refers specifically to "permitting the use of publicly accessible internal coverage criteria in *limited* circumstances [emphasis added]." The MA plan approaches we have reviewed or learned of to date, appear to broadly extend a flexibility that was intended for a

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specific, limited set of circumstances, which we do not believe applies to the criteria for inpatient admission. In our view, this gives MA plans carte blanche to continue applying inappropriate criteria that consistently results in patients being denied access to Medicare-covered services. This is directly contrary to the stated intent of the final rule to ensure that people with MA receive access to the same medically necessary care they would receive in Traditional Medicare. Accordingly, we urge CMS to clarify that coverage criteria for inpatient admissions are fully established under Traditional Medicare, as set forth in § 412.3, consistent with long-standing CMS policy under Traditional Medicare. We also urge CMS to explicitly clarify that the flexibility for MA plans to supplement Traditional Medicare rules with additional internal coverage criteria is not applicable for medical necessity reviews of inpatient admissions and level of care decisions and should only be used in certain *limited* circumstances.

2. Requirement for Coverage Criteria to be Publicly Accessible and Meet Certain Minimum Standards

In addition to our concerns about the inappropriate application of internal coverage criteria for inpatient admissions under the new rules, we also maintain that the use of InterQual and MCG criteria, or other similar products, fails to meet the public accessibility and evidentiary standards set forth in the final rule. CMS indicates that MA plans may create internal coverage criteria based on current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees and providers. As you know, InterQual and MCG are proprietary guideline tools which must be licensed for a fee. They are not publicly available.

Moreover, we maintain concerns about whether such proprietary tools actually meet the standard of evidence outlined in the final rule given the limited ability of clinical literature to appropriately distinguish between the need for inpatient care or observation at the point of admission for many diagnoses. Further, we believe substantive elements of the internal coverage criteria being applied by proprietary tools falls into a category of so-called evidence, which CMS explicitly prohibits in the final rule: "Evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization, or that does not comply with the standards described in the regulation would not represent proper justification for instituting internal coverage guidelines that would restrict access to care. These types of evidence have not undergone peer-review, are not transparent, or are not research methodologies that can plausibly establish causality." Accordingly, we respectfully request that CMS emphasize the requirements related to public accessibility and standards of evidence included in the final rule and take swift action to correct MA plan policies that do not comply.

3. Applying More Stringent Standards than CMS to Evaluate a Physician's Judgement Under the Two Midnight Benchmark

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Prior CMS guidance on reviewing short stay hospital claims for inpatient status under the two midnight benchmark indicates that Quality Improvement Organizations conducting medical reviews may review the entire medical record to "support or refute the reasonableness of the physician's expectation, but entries after the point of the admission order are only used in the context of interpreting what the physician knew and expected at the time of admission [emphasis added]." Aetna's recently published policy adopts this language but changes the CMS standard for interpreting "what the physician knew and expected at the time of admission" and instead, adopts its own, more stringent standard, of interpreting "what the physician reasonably should have known or reasonably should have expected at the time of admission [emphasis added]." This is an example of an MA plan changing CMS rules and applying more restrictive standards in a way that could be used to justify denials of inpatient care that would have been covered under Traditional Medicare. We urge CMS to review MAO policies like this in advance of Jan. 1, 2024, to identify policies which are inconsistent with CMS policies and practices, and again, take swift action to correct MA plan policies that do not comply with the new rule.

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Attachment B: Source Material

United Policy: Medicare Advantage Coverage Summary for Hospital Services (Outpatient, Observation, and Inpatient), published Nov. 1, 2023, to be effective Jan. 1. 2024:

https://www.uhcprovider.com/content/dam/provider/docs/public/policies/index/macs/hos pital-services-01012024.pdf

Aetna Policy: Medicare: CMS Final Rule – Two Midnight Rule Beginning January 1, 2024. This PDF document was distributed to network providers.



Medicare: CMS Final Rule - Two Midnight Rule

Beginning January 1, 2024

Beginning January 1, 2024, the Centers for Medicare & Medicaid Services ("CMS") will introduce regulations and changes related to Medicare Advantage plans ("MA Plans") prior authorization, coverage criteria and access to care, as set forth in the 2024 Part C and D Final Rule (the "Final Rule").¹² Aetna seeks to provide you with some information on how Aetna's MA Plans complies with the Two Midnight Rule.

Aetna's MA Plans Follow the Two Midnight Benchmark

- We will follow the Two Midnight Benchmark. Under the Two Midnight Benchmark, surgical procedures, diagnostic tests and other treatments will generally be considered appropriate for inpatient hospital admission and payment under Medicare when the physician expects the patient, based on specific complex medical factors documented in the medical record (such as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of adverse event), to require a hospital stay that crosses at least two midnights and admits the member to the hospital based upon that expectation.
- > Our MA Plans are not required to follow the Two Midnight Presumption.

Our Medical Necessity reviews

- We will review the stay to determine whether the inpatient admission was appropriate. The entire medical record may be reviewed to support or refute the reasonableness of the physician's expectation, but we will use entries after the point of the admission order to interpret what the physician reasonably should have known or reasonably should have expected at the time of admission.
- It is important that you provide us with detailed clinical records to support the physician's judgement.

Our MA Plans can use Internal Coverage Criteria to determine Medical Necessity

- We have created publicly accessible internal coverage criteria when coverage criteria are not fully established under the Medicare statute, regulation, national coverage determinations (NCD), or local coverage determinations (LCD).
- Our internal coverage criteria are based on current evidence in widely used treatment guidelines or clinical literature and comply with CMS requirements. These criteria will be available soon on <u>https://go.aetna.com/aetnamedicareguidance</u>.

We thank you for your continued partnership and hope this communication helps you in understanding Aetna's approach and commitment to compliance with the CMS Final Rules.

¹ Reviewing Short Stay Hospital Claims for Patient Status: Admissions On or After January 1, 2016 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare_PFS-Compliance_ Programs/Medicale.Review.Downloads/Reviewing-Short-Stay-Hospital-Claims-for-Patient-Status.pdf) (emphasis added).
² 2 Midright Inpatient Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013 (available at https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicalreview./downloads/gastorwebsiteposting_110413-v2-glean.pdf) (emphasis added).