California Hospital Association

January 27, 2025

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

Re: CMS-4208-P, Medicare and Medicaid Programs; Contract Year (CY) 2026 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

Dear Acting Administrator Wu:

On behalf of more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the Centers for Medicare & Medicaid Services' (CMS) proposals to increase oversight of the Medicare Advantage (MA) program and bolster beneficiary protections to ensure that Medicare beneficiaries have equal and appropriate access to Medicare-covered services. To that end, CHA is providing comments on the CMS proposed "Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program."

In California, a growing majority (56%) of Medicare beneficiaries are enrolled in Medicare Advantage Organizations (MAOs), with Medicare Advantage (MA) penetration as high as nearly 75% in some counties. Many of these beneficiaries are enrolled in high quality MAOs that are part of tightly integrated delivery systems that fulfill the promise of MA plans to provide cost effective care. However, as the senior population grows — and as our state moves to enroll our most vulnerable seniors and persons with disabilities into MA plans — it is critical that CMS take steps to ensure that all MAOs employ policies and practices that expand access to care, ensure care is provided in the most clinically appropriate setting, and align with providers' efforts to deliver timely and coordinated services across the continuum of care. Further, as enrollment in the MA program reaches record levels, it is more important than ever to establish and implement stronger beneficiary protections and oversight mechanisms to ensure these steps are being taken.

In addition, hospitals and health systems have written extensively to CMS and other federal agencies in recent years articulating serious concerns about the negative effects of certain MAO practices and policies that can impede patient access to care and harm beneficiaries. These include excessive use of prior authorization, inappropriate denial of medically necessary services that would be covered by traditional Medicare, use of overly restrictive or proprietary medical necessity criteria, inadequate

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provider networks, and unreasonable volumes of requests for additional information designed to delay care and payment, among others. These practices unequivocally impede patient access to health care services, create inequities in coverage between Medicare beneficiaries enrolled in MA versus those enrolled in traditional Medicare, and, in some cases, directly harm Medicare beneficiaries through unnecessary delays in care or outright denial of covered services. They also add billions of wasted dollars to the health care system and are a major driver of burnout among health care workers.[1]

CMS has taken important steps to advance and finalize rulemaking to address some of these issues, increasing oversight of MAOs and seeking to better align coverage offered by MAOs with traditional Medicare. However, more robust enforcement and transparency are needed to ensure compliance with important coverage protections designed to ensure seniors can depend on their private Medicare coverage when they need medical care.

Specifically, California hospitals and health systems continue to report non-compliance with certain CMS rules, including failure to adhere to the two-midnight benchmark, application of more restrictive criteria than traditional Medicare, and inappropriate denial of Medicare-covered post-acute care services, among others. With these challenges in mind, CHA strongly supports CMS' proposals to increase oversight of the MA program, including those that would fortify restrictions on MAO use of internal coverage criteria, strengthen appeal rights pursuant to an organization determination, adopt additional guardrails for MAO use of artificial intelligence (AI) and algorithms, and increase transparency of medical loss ratio reporting requirements, among others.

Specific comments with respect to these provisions, including strong support for proposals that strengthen consumer protection and patient access to care, as well as recommendations to improve enforcement and compliance with federal rules, are enumerated in the following sections.

Enforcement and Compliance with CMS Requirements

The findings of multiple federal legislative and oversight agency reports and investigations in recent years have credibly established serious concerns about beneficiary access to medically necessary care in the MA program.[2, 3, 4] **Greater scrutiny and enforcement of existing MA regulations is needed to help protect Medicare beneficiaries from inappropriate delays and denials of Medicare-covered services among certain plans.** As noted below, additional enforcement and compliance actions should focus on MAOs with a history of suspected or actual violations and those that have not consistently made good faith efforts to follow federal rules. Core elements of an enforcement and compliance strategy must include:

- **Data Collection and Reporting on Plan Performance.** Consistent with CHA's November 2024 letter to CMS, CHA supports CMS' previous proposals to increase MAO transparency and accountability by implementing additional data collection and audit procedures for utilization management policies and tools. There are currently limited data reporting mechanisms that provide CMS with information about plan-level coverage denials, appeals, and grievances, as well as delays in care resulting from plan administrative processes. These are important indicators of

[1] https://www.hhs.gov/sites/default/files/health-worker-wellbeing-advisory.pdf
[2] https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp
[3] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[4] https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf

beneficiary access and are necessary for meaningful oversight of MA plans. For example, plans with excessively high service and payment denial rates compared to other plans, or plans with unreasonably high beneficiary grievance rates, may be indicative of inappropriate behavior that warrants further inquiry or audit.

In addition, CHA recommends that existing MA plan data, which is submitted to CMS annually and must be audited by an outside organization, be used to a greater extent to guide oversight and enforcement activities. CMS could increase oversight by using existing data to identify MA plans for program audits that review whether the plan is correctly applying coverage policies or medical necessity criteria, requiring plans to report data quarterly, publishing a public list of MA plans subject to corrective action requirements, and/or incorporating organization determination data into star ratings.

- **Routine Auditing.** CMS conducts routine audits for some aspects of the MA program, such as for the purpose of risk adjustment data validation. Additional auditing is necessary to ensure compliance with CMS rules, especially those around medical necessity criteria needed to achieve the intended alignment between traditional Medicare and MA. Such audits should be focused on MA plans that are outliers in reported plan performance data or have a history of suspected or actual CMS rule violations on their record. With these factors in mind, CHA recommends that CMS regularly audit a sample of MA plan denials, using a similar methodology as the 2022 U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) report, to review MA plan determinations for the appropriate application of Medicare coverage rules and criteria. Without this level of detailed auditing, certain MA plans are likely to continue circumventing federal rules without detection, rendering the proposed beneficiary protections ineffective.

- **Pathways to Report Suspected Violations.** Hospitals and other health care providers often play an important role in helping patients navigate their health insurance benefits and are well-positioned to identify suspected violations of federal rules related to MAO coverage determinations. A formal, streamlined pathway for providers to report suspected violations — that would provide some level of accountability and transparency in addressing violations of CMS rules — is urgently needed. This should specifically include a formal pathway to submit procedural violations or complaints into CMS' Complaints Tracking Module (CTM). CMS should also consider publishing a redacted database of CTM complaints with their resolutions to increase public transparency into common MA complaints and how they are being addressed. Without a formal pathway and appropriate tracking mechanisms, providers may only have the plan's internal complaint pathway or the dispute resolution pathways outlined in their contract, which may lack external review or accountability. In the absence of a centralized complaint pathway, CMS has limited ability to establish a fact pattern needed to engage in enforcement activity or even be aware of potentially pervasive compliance problems that the agency is charged with addressing.

- **Appropriate Enforcement Action and Penalties.** Penalties are a necessary part of enforcement to incentivize compliance with CMS rules, especially for specific rules or plans with a history of non-compliance. CHA urges CMS to exercise its authority, where appropriate, in issuing warning letters and corrective action requirements to non-compliant MA plans based on the results of audits and plan-reported data. Additionally, if such non-compliance persists, CMS should impose intermediate sanctions (e.g., suspension of marketing and enrollment activities) and civil

monetary penalties — up to termination of the MAO's contract with CMS in cases where a plan does not make good faith efforts to comply. Each of these elements will be critical in ensuring the proposed changes and clarifications to existing CMS rules become standard operating procedures for MA plans and have the intended effects on beneficiary protection and access to care.

While appropriate enforcement action is necessary to ensure patient protection and efficient operation of the Medicare program, these actions should be targeted to MAOs with a history of suspected or actual violations or whose performance metrics related to appeals, grievances, and denials could be indicative of a broader problem warranting further investigation. As previously noted, many MA beneficiaries in California are enrolled in high quality MAOs that are part of tightly integrated delivery systems that are fulfilling the promise of MA plans to provide cost effective care. With this in mind, every effort should be made in carrying out enforcement activities to ensure that undue burden is not placed upon MA plans that consistently act in good faith and adhere to CMS rules.

Opportunities for Additional Scrutiny

While the recommendations thus far regarding enforcement broadly address the need to increase oversight and enforcement of federal MA regulations generally, there are specific provisions and issues that warrant greater scrutiny because they are difficult to enforce, are the most critical to ensuring meaningful reform of insurer practices that can inappropriately limit care, and/or because we have received reports of widespread non-compliance from our members. These include MAO adherence with the two-midnight benchmark, post-acute care access, readmission denials, and ensuring the relevant expertise of MAO clinician reviewers. In addition, MAO use of internal coverage criteria for medical necessity determinations continues to be a top priority issue that warrants additional scrutiny; this is discussed in detail in a subsequent section in response to CMS' proposed updates for 2026.

Two-Midnight Benchmark. In the CY 2024 final rule, CMS codified that MA plans are required to adhere to the two-midnight benchmark, referring to the inpatient admission criteria for traditional Medicare in 42 CFR § 412.3 used to determine whether inpatient care is medically necessary. This is an important step forward, as it requires that MA plans adhere to the same inpatient admission criteria as traditional Medicare. These criteria establish that inpatient level care is appropriate when the admitting physician expects the care to extend beyond two midnights, the service is on the inpatient only list, or the patient's condition qualifies as a case-by-case exception. However, CMS also clarifies that MA plans do not have to follow the two-midnight presumption, which refers to the directive to traditional Medicare reviewers to presume that inpatient stays that extend over two midnights are appropriate for inpatient care.

While California hospitals anecdotally report that they have had more frequent success in overturning inappropriate inpatient denials since the new rules took effect in 2024 than previously was the case, hospitals are still reporting widespread frustrations with the denial of inpatient hospital care that extended over two midnights (and frequently over multiple days). Many report little to no change in the volume of initial inpatient denials, even if a greater number of them are being overturned later in the appeals process. In addition, CHA members continue to describe cases where MA plans are downgrading multi-day hospital stays, including some that exceed a week, to observation status with practices that continue to be more restrictive than Medicare and are inconsistent with the two-midnight benchmark.

While CMS' proposals to fortify restrictions on MAO use of internal or proprietary coverage criteria will help to address some of these challenges, greater scrutiny and enforcement is needed to ensure

compliance with the two-midnight benchmark and parity of inpatient hospital coverage between MA and traditional Medicare. Among other potential enforcement actions previously described, CMS should also:

- Collect and monitor data on length of stay for observation cases between MA and traditional Medicare and denials of inpatient cases exceeding two days at the plan level.
- Conduct targeted audits of plans with outlier values for observation length of stay or long-stay inpatient denials.
- Examine in audits whether MA plans are appropriately only evaluating whether the admitting physician's judgment that the care would extend beyond two midnights was reasonable and appropriately documented in the medical record — or whether additional factors or criteria are being applied indiscriminately that are inconsistent with CMS rules.

Post-Acute Care Access. Hospitals and health systems in California continue to report persistent challenges with MAO practices that inappropriately deny MA beneficiaries access to covered post-acute care services. These challenges remain unresolved despite CMS rulemaking and clarifying guidance specifically addressing MAO obligations to provide access to post-acute care services consistent with Medicare coverage requirements. In fact, a 2023 survey of CHA members found that patients with MA plans are nearly twice as likely to experience a discharge delay than those with traditional Medicare, raising concerns about access to Medicare-covered post-acute care services for MA enrollees.[5] In fact, one CHA member reports that 56% of MA authorization requests for long-term care hospital (LTCH) admissions are initially denied by MA plans. One particular large national MA plan denied 77% of initial LTCH requests from this health system in 2024. A majority of these denials were ultimately overturned after labor-intensive appeals suggesting they were incorrect to begin with.

These findings and experiences have been further corroborated by a 2022 report from the HHS-OIG on MAO use of prior authorization, which found disproportionately high rates of inappropriate denials for post-acute care, as well as a more recent report from the U.S. Senate Permanent Subcommittee on Investigations, which found that post-acute care is subject to excessive rates of prior authorization review and denials that have increased in recent years.[6,7] In response, the HHS-OIG recently announced an investigation into MA plan prior authorization practices and the impact post-acute care access.[8]

Given the well-documented history of inappropriate post-acute care denials, it is vital that CMS make post-acute care a priority in its audits and oversight of utilization management practices of MAOs. This should include reviews of the criteria being used by MA plans, the rationale provided for denials, and evaluation of whether clinician reviewers have appropriate medical training and expertise in post-acute care as required by current regulations. In addition, MA plans should be required to report detailed data to CMS regarding the outcomes of post-acute care admission determinations, as well as the turnaround time for these decisions, which is especially consequential for hospitalized patients.

[5] https://calhospital.org/wp-content/uploads/2024/01/Impact-of-Inadequate-Networks-CHA-Analysis-FINAL.pdf
[6] https://oig.hhs.gov/reports/all/2022/some-medicare-advantage-organization-denials-of-prior-authorization-requests-raise-concerns-about-beneficiary-access-to-medically-necessary-care/
[7] https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000873.asp
[8] https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000873.asp

Readmission Denials. Hospitals and health systems in California have raised concerns about growing MAO readmission denials using criteria that are inconsistent with and more restrictive than traditional Medicare. Oftentimes, plans cite that the reason for denial of an inpatient hospitalization is a readmissions payment policy, contending that the denial is not a medical necessity or coverage determination. Doing so circumvents CMS protections that prohibit retrospective denial of coverage or payment for pre-authorized services on the basis of medical necessity and applicable appeal rights for an organization determination. In addition, certain plans are routinely using their own criteria to deny coverage and payment for hospital readmissions through denial of prior authorization for inpatient hospitalization, reduction in the approved level of care to observation, or through combining an initial and subsequent hospital stay into a single admission and claim to reduce payment. In other cases, certain MAOs deny full payment for a subsequent admission with 30 days of an initial readmission regardless of the medical appropriateness of the readmission. Each of these circumstances results in a denial of a basic Medicare benefit for inpatient hospital services with criteria more restrictive than Medicare, which is explicitly prohibited by current CMS regulations. More troubling, certain MAO practices that result in premature termination of coverage for continued hospital care or refusal to authorize the level of post-acute care required to safely manage the patient's condition at the time of hospital discharge are, in some cases, the cause of the patient's readmission. Yet, in these instances, the MAO penalizes the hospital for a readmission that was caused by the MAO's own refusal to approve care the patient needed upon discharge.

Notably, the growth in this specific type of readmission denial curiously coincides with CMS having increased the weight assigned to plan all-cause readmissions in the MAO star ratings program beginning with 2023 data for 2025 star ratings. This means that plan performance on readmission rates will have a much larger impact on MAOs' overall star rating and quality bonus payments. The practices of certain MAOs that have aggressively increased readmission denials in tandem with the financial incentive presented by a re-weighting of the MAO star rating readmission measure should be further investigated by CMS.

Additionally, to address these circumstances through regulation, CMS should consider explicitly clarifying the following:

- **MAOs may *only* apply the plain language of CMS rules to evaluate the appropriateness of repeat admissions**, specifically those in the Medicare Claims Processing Manual (100-04 Chapter 3, Section 40.2.5) and the Quality Improvement Organization Manual (100-10 Chapter 4, Section 4240) and may not supplement this guidance with additional criteria more restrictive than traditional Medicare.
- **The definition for medically unnecessary readmission is governed exclusively by Social Security Act § 1862(a)(1)** (that is, the admission was not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member), and no alternate or more restrictive definitions may be used by MAOs in evaluating the medical necessity of a hospital readmission.
- **MAOs are prohibited from claiming a premature discharge as the basis to deny a hospital readmission when the MAO denied coverage or payment for continued hospital care during the initial stay or when the MAO did not authorize the level of post-acute care required to safely manage the patient's condition at the time of hospital discharge**. Premature discharge is one of the codified reasons that a readmission can be determined to be medically unnecessary according to CMS standards previously specified. Accordingly, MAOs should not be able to identify premature discharge as the reason to deny payment for readmission when the premature discharge was the result of the MAO terminating inpatient coverage against the treating

physician's advice. To further protect against this scenario, CMS should also clarify that **any premature discharge that was the result of an MAO's refusal to continue to authorize hospital care must be excluded from the definition of medically unnecessary readmission**.

Relevant Expertise of MAO Clinician Reviewers. The CY 2024 MA final rule requires clinicians rendering adverse medical necessity determinations to have sufficient training and experience in the particular field of medicine related to the denied item or service. This provision is an important improvement to MAO processes, which previously were not subject to any rules or requirements about the qualification of the MAO clinician overruling the recommendation of the patient's treating physician to deny recommended care.

It has been a longstanding and pervasive problem that health plan reviewers without applicable expertise in the requested service discipline are issuing denials for medically necessary patient care. In other cases, health plan reviewers without appropriate expertise are participating in peer-to-peer consults with the treating physician and are empowered to make definitive decisions about patient access to prescribed treatments, overriding the judgment of a physician with more specialized expertise who has had the benefit of examining and assessing the individual patient's circumstances. This problematic dynamic plays out across a number of medical specialties and is especially common for post-acute care admissions, where a clinician without expertise in any rehabilitative discipline overrules the judgment of a treating physician who specializes in rehabilitative care.

While recently implemented CMS regulations seek to ensure health plan clinicians reviewing requests for services have appropriate training and expertise, challenges persist with enforcement and compliance. This is largely because MA plans are not required to identify the clinician reviewing the determination and the reviewer is not required to sign the denial, making it nearly impossible to identify the person who reviewed the denial and whether they have the appropriate credentials or training as required by CMS regulations. Some plans have reviewers sign denials; others use only clinician initials; and others do not include any type of signature or initial. It is unclear how the requirements to ensure the appropriate medical training of clinician reviewers can be validated if patients and providers are unable to identify the person who reviewed the denial. Accordingly, **CMS should supplement § 422.566(d) with additional specifications to require identification of clinician reviewers and create standardized pathways for patients, providers, and CMS to assess whether clinicians issuing organizational determinations meet CMS' requirements. This should include CMS conducting routine audits of the credentials of MA plan clinicians reviewing and signing organizational determinations to validate compliance with CMS regulations**.

Fortifying Requirements for Internal Coverage Criteria

In the CY 2024 MA final rule, CMS codified that MA organizations must make medical necessity determinations in accordance with all traditional Medicare coverage requirements, including rules established in statute, regulation, National Coverage Determinations (NCDs), and Local Coverage Determinations (LCDs). Further, the CY 2024 rule establishes that MAOs may only utilize internal criteria when Medicare coverage criteria are not fully established under traditional Medicare. In such instances, MA organizations may utilize internal coverage criteria if it (a) is publicly available, (b) is based on current evidence in widely used treatment guidelines or clinical literature, and (c) indicates how 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. These updates are important protections to

ensure MA beneficiaries have equal access to Medicare-covered services and are not denied care as a result of more restrictive plan rules or policies.

However, despite the final rule and subsequent clarifying guidance from CMS, MAO use of proprietary medical necessity criteria that are more restrictive than traditional Medicare and not transparent to patients or providers continues to be a pervasive problem in the MA program. Hospitals and health systems continue to report that many MAOs consistently fail to meet some or all of the requirements for using internal coverage criteria codified at § 422.101(b)(6). This includes instances of the criteria not easily or publicly accessible, utilizing sources that are neither widely used guidelines nor peer-reviewed literature, and altogether ignoring the requirement to demonstrate that the additional criteria used provide an identifiable clinical benefit that outweighs potential patient harm from delayed or decreased access to services. Indeed, the persistent use of proprietary or internal coverage criteria continues to result in inappropriate denials and reduced access to Medicare-covered services — the very problem the CY 2024 final rule sought to address.

With these challenges in mind, CHA appreciates CMS' specific proposals to increase oversight of MAO use of internal coverage criteria in the CY 2026 proposed rule, as well as in CMS' previously proposed Medicare Part C Utilization Management Annual Data Submission and Audit Protocol released in September.[9,10] CMS' discussion in the rule's preamble regarding common misunderstandings and misapplications of the coverage criteria provisions that took effect Jan. 1, 2024, and CMS' response in proposing to define the term "internal coverage criteria" and establish additional guardrails for their use is appreciated. **These guardrails will help to promote transparency and consistency in the criteria used to make medical necessity determinations for Medicare beneficiaries and have the potential to make meaningful advancements in patient access to care if paired with appropriate agency enforcement and compliance actions**.

Specifically, **CHA supports CMS' proposals** to:

- **Define internal coverage criteria at 422.101(b)(6)(iii)**.[11] Given that certain MA plans continue to cite proprietary products and criteria to deny inpatient level of care, a definition of internal coverage criteria is a helpful tool to stipulate exactly what constitutes the criteria being regulated and restricted. The proposed definition is sufficiently broad to include "any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party" and that it specifically includes "any coverage policies that restrict access to or payment for medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness."
- **Require MA plans to identify the plain language of the applicable Medicare coverage and benefit criteria they are interpreting or supplementing in circumstance where it is permitted**. The plain language summary of the criteria being interpreted must be publicly available and

[9] https://www.regulations.gov/document/CMS-2024-0292-0001

[10] https://calhospital.org/wp-content/uploads/2024/11/CHA-Comments-Medicare-Advantage-UM-Data-and-Audit-PRA_final-11.12.2024.pdf

[11] CMS proposes to define internal coverage criteria as any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable Medicare statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination at § 422.101(c)(1). This includes any coverage policies that restrict access to or payment for medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness.

provide an explanation of the rationale that supports the adoption and application of the internal coverage criteria. This will help to increase transparency and accountability for the circumstances where MAOs are applying internal coverage criteria and to ensure that it is not applied inappropriately or more broadly than intended.

- **Clarify that internal coverage criteria may only be used to supplement or interpret already existing content within the Medicare coverage and benefit rules**. CMS' clarification prohibits MAOs from adding new, unrelated coverage criteria for an item or service that has existing, but not fully established, coverage policies. This is an important distinction given certain MAOs have continued using proprietary or internal coverage criteria as a blanket policy when making medical necessity determinations, citing regulatory flexibilities that allow MAOs to supplement or interpret Medicare criteria in certain limited circumstances. This clarification will ensure that MAOs cannot add new or unrelated coverage criteria that create new requirements for coverage parallel to or in excess of the Medicare standards.
- **Prohibit use of internal criteria to automatically deny coverage of basic benefits without the MAO making an individual medical necessity determination based on the patient's individual circumstances and medical condition**. Existing regulations require MAOs to take a patient's individual circumstances and medical condition, including the recommendation of their treating physician, into consideration when making a medical necessity determination. The advent of automated tools that can facilitate denial of Medicare-covered services without regard to these specific factors has been problematic in some cases. This proposed update is an important clarification to help prevent automated denials of coverage or use of algorithms that lack the required due process and may impede patient access to covered services.
- **Prohibit MA plan coverage criteria when it does not have any clinical benefit to the patient and exists only to reduce utilization to the item or service**. CHA agrees that the primary purpose of clinical criteria is to ensure that safe, appropriate, and medically necessary health care services are provided to patients; any clinical criteria that exist solely for the purpose of reducing utilization violates this patient-centered principle and may harm enrollees by inappropriately denying medical care for the financial benefit of an insurer. Criteria that are exclusively designed to reduce utilization should be explicitly prohibited.
- **Add additional specifications to the requirements for public accessibility of internal coverage criteria.** CHA strongly supports CMS' proposals to require each internal coverage criterion used by an MAO to be listed and identified by the MA plan and to appropriately distinguish circumstances where an MAO is supplementing or interpreting traditional Medicare criteria that are not fully established. The additional specifications requiring MAOs demonstrate how their internal coverage criteria meet CMS standards for public accessibility and high-quality evidence, including requiring citations for the evidence that support the criteria, are important steps forward in improving transparency and consistency in the use of internal coverage criteria.

In addition, CMS should consider the following policy options to further strengthen the protections and clarifications regarding internal coverage criteria:

- **Requiring MA plans to include notification on denial letters to alert patients and providers in cases where additional coverage criteria were used to support an adverse determination**. The notification should explain why additional criteria were needed to supplement general provisions in making a medical necessity determination and specifically how those criteria were applied to the patient's individual circumstances.
- **Requiring MA plans to report data to CMS on the number and percentage of overall medical necessity reviews where the plan applied additional coverage criteria to supplement**

Medicare provisions. This is critical to understanding whether plans are using their own criteria in only the limited circumstances CMS intended or whether this flexibility is being overextended.

- **Publishing additional guidance on CMS' interpretation of the limited set of circumstances where criteria under traditional Medicare are not fully established**. It is important that CMS be the ultimate arbiter of when traditional Medicare criteria are fully established, and therefore, when MAO use of internal coverage criteria is prohibited. MAOs should not have the discretion to dictate what the applicable Medicare rules are for a given service or item and self-report whether there is permissible flexibility to apply additional criteria. For these reasons, and to prevent MAOs from adopting various divergent interpretations of when Medicare criteria are fully established that create confusion and inconsistencies in coverage across plans, CMS is encouraged to consider additional clarifying guidance.
- **Applying CMS standards for the development of LCDs by Medicare Administrative Contractors for development and approval of MAO internal coverage criteria**, including requirements for public notice and comment during criteria development. To promote greater parity in coverage between traditional Medicare and MA as intended, the process for developing and approving the criteria used to make coverage determinations should be treated similarly with consistent requirements.
- **Clarifying that the proposed definition of internal coverage criteria applies to any such "policies, measures, tools, or guidelines" used for the purposes CMS describes regardless of the term or label each plan may use to describe their criteria**. Some MAOs continue to refuse to share internal coverage criteria with providers indicating that the criteria are "protocols," not criteria, and therefore are not subject to public disclosure under existing regulations. This loophole should be closed.
- **Providing a link to an MAO's internal coverage criteria website on Medicare Plan Finder** so prospective enrollees can better understand how a plan makes coverage decisions at the time of plan selection.
- **Establishing an MA Coverage Database analogous to the Medicare Coverage Database**, which would enable searching internal coverage criteria across plans and in specific jurisdictions that can enhance transparency for both patients and providers.

In implementing CMS' various proposals to fortify guardrails regarding MAO use of internal coverage criteria, if finalized, CHA also recommends that CMS ensure appropriate alignment of reporting requirements to reduce duplication or unnecessary administrative burden for the health care system. In tandem with CMS' proposed Medicare Part C Utilization Management Annual Data Submission and Audit Protocol, the proposals in this rule have the potential to create overlapping reporting requirements, necessitating the reporting of similar data elements in various different formats. **Every effort should be made to streamline reporting on internal coverage criteria to ensure that information reported is readily available, easily understandable at the plan and service level, and does not create duplicative requirements that could be unnecessarily burdensome or confusing to patients, providers, or other stakeholders**.

Finally, CMS proposes to remove the requirement at §422.101(b)(6)(i)(A) that additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. While CHA recognizes and understands CMS' comments that adherence with this standard is difficult to establish with evidence and challenging to enforce, **CMS should *not* remove this important codification that establishes clinical benefit to the patient as the central objective of medical necessity determinations**. The proposal to remove this standard in regulation is

especially concerning given CMS' own observation that there are "numerous instances of MA organizations simply and baldly stating that their internal coverage criteria provide clinical benefits that are highly to outweigh any clinical harms … [without] much in the way of evidence in the information provided by the MA organizations that definitively proves this to be true." **Systemic non-compliance with CMS policy should result in stronger enforcement and appropriate clarifications to strengthen adherence — not withdrawal of the standard**. In addition to finalization of the previously discussed proposals, agency guidance and clarification may be helpful to expand upon the requirement for criteria to provide clinical benefit to the patient.

In addition, CMS asks for stakeholder input on whether the clinical benefit standard could be replaced with a standard focused on whether internal coverage criteria promote patient safety. **While CHA supports the further additive inclusion of patient safety in this standard as proposed, patient safety should not be a replacement for the standard requiring internal criteria to provide clinical benefit to the patient**.

Strengthening Medical Loss Ratio (MLR) Reporting Requirements

To improve CMS oversight and better align agency reporting requirements for MA with commercial and Medicaid requirements, CMS proposes several changes to MLR requirements for MA and Part D plans. The rule would require plans to submit detailed reporting information on how plans calculate the MLR and allocate expenses, reinstating requirements previously in place; standardize activities that can be counted as a quality improvement activity (QIA) in the numerator of the MLR calculation; and establish an MA and Part D MLR audit process to ensure the accuracy of MLR reporting.

CHA supports CMS' proposals to strengthen and increase oversight of MLR reporting requirements and establish an MLR auditing program to ensure compliance. The MLR standards are important oversight tools to ensure that health care premium dollars are predominately used to pay for enrollees' health care needs and not inappropriately extracted in excess profit or administrative costs. CHA shares CMS' concern regarding inconsistent methods for insurer determinations of which expenses can be included as a QIA in the MLR calculation's numerator. The inclusion of additional or inappropriate expenses in the MLR numerator can artificially inflate an MAO's MLR. This allows the plan to more easily meet the MLR standard while undermining the MLR's purpose, which is to incentivize plans to reduce administrative costs and decrease funding for activities such as marketing, profits, and other business functions that do not explicitly provide value for taxpayers and beneficiaries. With these challenges in mind, **CHA supports CMS' proposed audit program to examine MAO MLR submissions and evaluate compliance with federal rules**. This is an important enforcement mechanism to ensure MA plans and Part D sponsors are appropriately spending funds to provide care to enrollees.

With this in mind, CHA supports CMS' proposal to clarify and strengthen requirements that only expenditures directly related to activities that improve health care quality be included as "quality improving activity expenses" for the purpose of MA MLR reporting. In addition, for further clarity, CMS should consider specifying that reviews based upon MA plan payment or reimbursement policy — or any substantively comparable programs whose purpose is to deny, reduce, or downcode coverage and payment of services either concurrently or retrospectively — are *not* quality improvement activities for MLR purposes. For example, certain MA plans conduct retrospective reviews to deny coverage and payment for hospital stays within 30 days of a prior hospitalization under the guise of a quality review. These are not quality activities, but rather reimbursement reviews designed to reduce coverage and payment. **While utilization management programs are already excluded from the definition of QIAs,**

CMS should further clarify that concurrent or retrospective payment reviews are not QIAs for the purpose of calculating MLR and include review of these activities in the scope of the proposed audit program.

In addition, CMS requests stakeholder comment on how the MA and Part D MLRs are calculated and overseen with respect to vertically integrated systems and organizations. As CMS notes, there are well-established concerns that MLR reporting may be less transparent for large, vertically integrated organizations that may obscure payments between related entities, allowing the plan to meet its MLR target but not appropriately reflecting profit made by the system or organization as a whole. This is a particular challenge and concern for large, national insurer conglomerates that own pharmacy benefit managers and a variety of related entities. For example, UnitedHealth Group has so many subsidiaries that, in 2023, it paid itself $136 billion. More than 25% of UnitedHealth Group's total revenues come from transfers from one side of its balance sheet to another.[12] Manipulation of the MLR calculation can occur when insurer conglomerates count potentially extraordinary dollars paid to themselves and affiliated entities as qualified care expenses rather than sending those dollars back to enrollees or otherwise using them to pay for health care services. Such practices circumvent the goals of the MLR requirements and are potentially harmful to patients and consumers. We support efforts to better understand MLR calculation for vertically integrated insurers and appropriately distinguish where integration creates value for consumers, as opposed to circumstances where it results in excess profit being extracted from the health care system.

Guardrails for Insurer Use of Artificial Intelligence

The proposed rule highlights the increased use of AI in health care and warns of the potential for these technologies to exacerbate biases and inequities if left unchecked. The proposed rule seeks to ensure that MA plans continue to provide equitable access to services, irrespective of technological advances, by updating existing regulations to account for the use of AI and other automated systems. This includes clarifications that MA plan use of AI or automated systems must comply with existing laws and regulations that prohibit discrimination against beneficiaries based on any factor that is related to health status or condition.

CHA recognizes that using algorithms or other AI models and systems can help increase the speed and accuracy of processing claims while more efficiently detecting fraud and ensuring program integrity. However, additional protections and guardrails are needed to ensure that the use of such tools do not impede equitable access to health care services. With this in mind, **CHA strongly supports CMS' proposals to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems, and that AI or automated systems used by MAOs may not discriminate on the basis of any factor that is related to the enrollee's health status**. CHA also supports CMS' proposal to codify that MAOs will be held responsible for compliance with these provisions when they contract with a third party or vendor for services that are furnished with an AI tool or automated system.

In addition, hospitals and health systems in California have reported concerns with certain AI tools or software that can automatically deny large volumes of claims or develop predictions that are used to justify termination of coverage for certain benefits at the date or time the tool predicts the patient will

[12] https://www.aha.org/aha-news/2024-04-30-aha-advertorial-unitedhealth-group-too-big-fail

no longer require services — for example, AI tools that predict how many days an MA enrollee will need care in an inpatient rehabilitation or skilled nursing facility before being ready for discharge. In some cases, these tools appear to be used as a de facto coverage determination whereby services are terminated on the date predicted without considering the patient's individual circumstances or their treating physician's recommendation. In fact, a recent report from the U.S. Senate Permanent Subcommittee on Investigations highlights specific concerns about the inappropriate use of automated tools that increased denials and reduced access to post-acute care in the MA program.[13] These practices raise serious concerns about access to care for MA beneficiaries and parity with coverage under traditional Medicare where such tools are not used.

Accordingly, **CHA recommends CMS consider additional safeguards to address concerns about how AI tools could restrict or deny access to medically necessary care for beneficiaries enrolled in MA plans as the technology continues to evolve.** These include:

- Establishing clear and transparent standards and guidelines for the validation, implementation, and continuous evaluation of automated claims processing software by MA plans in consultation with relevant stakeholders, such as beneficiaries, providers, regulators, and other experts.
- Ensuring that CMS oversight processes capture information on how plans use AI and other predictive technologies to make prior authorization determinations and audit the data to ensure that the use of AI does not result in determinations that are more restrictive than traditional Medicare requirements.
- Requiring MA plans to disclose the use and performance of automated tools in claims processing or medical necessity determinations to beneficiaries, providers, regulators, and the public, including the software's criteria, data, algorithms, and outcomes.
- Ensuring MA plan compliance with CMS guidance that requires considering the patient's individual circumstances and their medical team's recommendations in making coverage determinations and that these important factors are not overridden by automatic or algorithm-assisted denial software.
- Providing adequate resources and support for MA beneficiaries and providers to challenge and appeal erroneous or unfair denials or reductions of services because of auto-denial software, such as through independent review entities or ombudsman programs.
- Ensuring that software facilitating algorithm-assisted denials are not operating independently without the required level of human review by an appropriate clinician in the case of an adverse organizational determination. Such processes should ensure that algorithm-assisted denials are not simply rubber stamped by a human reviewer, but that a physician is engaging in meaningful review of the case and applicable criteria, taking adequate time to review and offer independent medical judgment.
- Considering how the use of artificial intelligence, automated systems, and patient care decision support tools used by MAOs would be able to comply with the public accessibility requirements and evidentiary standards outlined at 42 C.F.R. § 422.101(b)(6).

Provider Directory Requirements

CMS proposes to require MA plans to report provider directory data to CMS for incorporation into the agency's Medicare Plan Finder (MPF) platform — an online resource designed to aid enrollees in selecting

[13] https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf

Medicare coverage. The rule would also require MA plans to attest to the accuracy of provider directory information.

CHA strongly supports policies designed to ensure patients have accurate and comprehensive information about their Medicare coverage options to enable consumers to make informed enrollment decisions for themselves and their families. Providing consumers with more timely and accurate information about provider networks in tools used to inform coverage selection is an important step forward in achieving this aim. Improving consumer access to information about Medicare coverage options is more important than ever as enrollment in MA continues to grow and the complexity of coverage options continues to increase. For example, in 2024, the average MA beneficiary had access to 43 different MA plans in their geographic area, offered by an average of eight different insurers.[14] Further, an important factor for many patients in selecting a plan is ensuring that they can continue to access their regular medical care team, including doctors and hospitals with their selected insurance plan. Providing Medicare beneficiaries with provider network details at the time of plan selection can aid patients in selecting a plan that best meets their coverage needs and preferences. Accordingly, **CHA supports augmenting MPF with information on provider networks in addition to details on plan benefits, premiums, deductibles, and currently required**. CHA also supports proposals that would require plans to meet data compliance and quality checks and ensure the data are updated no later than 30 days after notification of a change in provider information or participation.

In addition, **CMS should also consider whether MAO utilization management program metrics that are meaningful indicators of patient access, such as appeals, denials, and grievances, should be included in the MPF to further aid consumers in making informed decisions about coverage options**. For example, the metrics that CMS proposes to require MAOs to report related to prior authorization and health equity at § 422.137(d)(6)(iii)(A) through (H) by service line should be incorporated into publicly available materials, including the MPF, that consumers can review when making coverage decisions.

Finally, with the ultimate goal of ensuring that accurate information about provider network participation is available to consumers, CHA recommends that CMS aggregate, validate, and populate this information in the MPF with data already reported to the agency under existing requirements, as opposed to creating new MAO reporting requirements that may be duplicative or create potentially divergent sources of network information.

Clarifications on Organization Determinations and Appeal Rights

CMS proposes several modifications to strengthen enrollee appeal rights afforded under Subpart M pursuant to an organization determination made by an MAO.[15] **CHA supports these proposals, which seek to further protect beneficiaries and ensure that appropriate remedies, including appeal, are available to patients when an MAO denies care**. Specifically, CHA supports CMS proposals to:

- **Clarify that the timeframe of a denial decision (whether pre-service, concurrent to service, or post-service) does not change the fact that a denial, including level of care decisions for inpatient or outpatient coverage, is an organization determination for which enrollees must be provided notice and afforded Subpart M appeal rights**. CMS cites instances of MAOs inappropriately denying

[14] https://www.kff.org/medicare/issue-brief/medicare-advantage-2024-spotlight-first-look/

[15] Existing regulations at part 422, subpart M, set forth the administrative appeals process available to enrollees who wish to dispute an organization determination made by an MA organization.

enrollee appeal rights for in-network inpatient services by ignoring enrollees' concurrent inpatient appeals, refusing to issue the required Notice of Dismissal, and failing to refer the appropriate cases to the CMS Independent Review Entity (Maximus) as required. This deprives MA beneficiaries of due process, enables the MAO to avoid paying for inpatient care rendered to an enrollee, and precludes CMS from having any visibility into these actions. Accordingly, clarifying that inpatient level of care determinations that occur concurrently, prior to service completion, or after service completion are organization determinations subject to applicable appeal rights is an important enrollee protection that closes several loopholes certain plans have exploited to deny coverage and payment for inpatient hospital admissions.

- **Require that a provider who has made a standard or expedited organization determination request on an enrollee's behalf, or when it was otherwise appropriate, receives notice of the MA organization's decision**. Hospitals and health systems regularly support patients in navigating their health insurance benefits, including requesting prior authorization and appealing inappropriate denials. Health care providers are often best positioned to receive, explain, and act upon an MAO organization determination in a timely way and often play a critical role in helping patients to secure insurance coverage of necessary medical treatments. Accordingly, CHA supports CMS' proposal to ensure that an enrollee's provider is notified of an MAO organization determination, where appropriate, in circumstances that the patient gave consent for the provider to appeal on their behalf. This can be particularly important where medical expediency is required in the case of an inpatient admission decision and MAO determinations are made on an expedited basis.
- **Removing an MAO's discretion to routinely reopen an approved authorization for an inpatient hospital admission.** The decision to admit a patient to the hospital is based on the treating physician's judgment that the care required to treat the patient's condition will extend over two midnights — or that the case meets one of the other criteria or exemptions codified at § 412.3(2) or (3), such as the procedure being designated as appropriate for inpatient only. This is assessed based on the information available *at the time of the admission decision* regarding complex medical factors documented in the medical record. Per the Medicare Benefit Policy Manual, Chapter 1, post-admission information can only be used to "support a finding that an admission was medically necessary." Accordingly, MAOs should not be able to reopen approved authorizations by adding new and material evidence that is available after-the-fact. Such reversals of previously approved hospitalizations are inconsistent with Medicare policy and serve as another loophole pathway for certain MAOs to deny coverage and payment for basic benefits provided to enrollees.
- **Clarify that an enrollee's further liability to pay for services cannot be determined until an MA organization has made a determination on a request for payment.** Existing regulations at part 422, subpart M, set forth the administrative appeals process available to enrollees who wish to dispute an organization determination made by an MAO. The regulations state that if an enrollee has no further financial liability to pay for services that were furnished by an MAO, a determination regarding these services is not subject to appeal. However, CMS expresses concern about some MAOs, which "improperly label adverse coverage decisions as 'contractual denials' or 'payment decisions' even though no request for payment has been submitted, [while], oftentimes, the services are still being rendered at the time of the MA organization's decision." CMS goes on to describe circumstances where certain MAOs denied enrollee coverage for ongoing inpatient services being received in a contracted hospital and erroneously concluded that the enrollee did not have an appealable interest because they would not be financially liable for more than applicable cost-sharing — even though it should be impossible to make such a determination of patient financial liability prior to the submission and adjudication of a claim. Enrollees in this circumstance are left without an opportunity to appeal decisions that directly affect their immediate medical care, and the denial can also have

implications for patient cost-sharing obligations if the level of care is changed from inpatient to outpatient during the hospital stay.

To remedy these situations, CMS proposes to clarify that the limitation on an enrollee's right to appeal due to not having a financial interest is only applicable if there has been a claim payment determination, which necessarily requires a submission of a claim from a contracted provider. This is intended to preserve an enrollee's right to appeal a coverage determination while receiving a Medicare-covered service, such as during an inpatient hospital stay, up to the point of claims processing where a determination of payment and cost-sharing liability can be made. CMS notes that coverage decisions, whether approved or denied, will continue to be subject to the Subpart M appeals process, and an enrollee would retain these rights until the MA organization makes a determination in response to a contracted provider (or enrollee's) request for payment. **CHA supports these proposed modifications to preserve and strengthen enrollee appeal rights, especially in cases where inpatient hospital admissions are downgraded or denied**.

However, it is important to raise that while this proposal is a step in the right direction, it does not address situations where MAOs make organization determinations after claim submission. This includes a wide array of denial types, such as diagnosis-related group downgrades, clinical validation denials, cost outlier line-item denials, and readmission denials, which meet the definition of organization determination, but often (and for some, by definition), occur after claim submission. Under this proposal, enrollees and their contracted providers will still have no CMS administrative remedy to appeal any of the multitude of denial types that occur after claim submission under Subpart M. **Given the growth in post-service claim denials and the tactics of certain MAOs to circumvent CMS rules governing coverage determinations by labeling them as payment policies, there is strong reason for CMS to fortify enrollee and provider appeal rights that occur *after claim submission*.** Without further CMS intervention, many types of denials for coverage and payment that occur *after the claim* will continue to be invisible to CMS and affected parties will have no appealable interest to remedy them.

Other Provisions Designed to Enhance Patient Access and Consumer Protections

As the MA program continues to grow and concerns about patient access to care in the MA program mount, greater oversight and scrutiny is needed to ensure that consumers are protected from policies and practices that may serve the financial interests of MAOs at the expense of enrollee access to care. There is a suite of policies in the proposed rule that seek to tighten regulations, close gaps in oversight, fortify consumer protections in the MA program, and better integrate care for complex and vulnerable patient populations. CHA supports these proposals that are designed to strengthen consumer protection and access to care.

Oversight of Agent and Broker Marketing Activity. CMS notes that it continues to receive complaints related to MA agent and broker marketing activities, including advertisements that are confusing or misleading, and attempting to draw an individual's attention to a specific plan or plans and unduly influence their enrollment decisions. Since 2023, CMS has issued denials for more than 1,500 TV ad submissions that were non-compliant and misleading to consumers. With this in mind, CHA supports the agency's proposal to enhance oversight of marketing and communications materials and increase the number and type of advertisements that are required to be submitted to CMS and subject to review before their use. These proposals would further advance the goal of ensuring that consumers have accurate and comprehensive information about their Medicare coverage options and that current or

prospective enrollees are not receiving misleading, inaccurate, or confusing information from MA agents or brokers.

Oversight of Supplemental Benefits. Given the growing share of taxpayer dollars funding supplemental benefits — a projected $79 billion in 2026 — CMS proposes to better understand how supplemental benefits are being used and provided to enrollees, and the experiences and outcomes of enrollees who use them. Specifically, CMS proposes to establish guardrails on the use of debit cards for accessing plan-covered supplemental benefits, including ensuring that debit cards are not inappropriately used as a marketing tool that may influence enrollment decisions. CHA supports additional oversight in these areas to ensure responsible management of supplemental benefit and rebate dollars, and specifically to ensure that health care dollars and taxpayer funds are being used appropriately to pay for enrollees' covered health care services as intended.

Limiting Cost-Sharing for Behavioral Health Services. The proposed rule seeks to improve access to behavioral health for enrollees by ensuring that in-network cost-sharing for behavioral health services is no greater than cost-sharing for those services in traditional Medicare. It also proposes zero cost-sharing for opioid treatment program services. Lowering patient costs helps to reduce barriers for patients with behavioral health conditions and promote timely access to potentially life-saving services. Accordingly, CHA supports the proposed updates to enrollee cost-sharing requirements to limit MA enrollee cost-sharing for behavioral health services.

Integration of Care for Dually Eligible Enrollees. California is home to 1.4 million individuals dually eligible for both Medicaid (Medi-Cal) and Medicare.[16] Under California's ongoing Medicaid reform initiative, California Advancing and Innovating Medi-Cal (CalAIM), dually eligible beneficiaries will be encouraged to enroll in Dual Eligible Special Needs Plans (D-SNPs) aligned with a Medi-Cal managed care plan. While many Californians enrolled in Medi-Cal participate in high-quality MAOs that are part of tightly integrated delivery systems, some managed Medi-Cal plans have limited experience administering benefits, raising concerns about integration and access to care. For example, certain D-SNP practices, such as erroneously applying Medi-Cal utilization management and prior authorization criteria to Medicare-covered services in a way that is more restrictive than traditional Medicare, creates inappropriate barriers for dually eligible enrollees. CHA supports CMS' proposals that seek to better integrate care for D-SNP enrollees and reduce administrative burden, such as providing enrollees with a single identification card for both their Medicaid and Medicare coverage and requiring D-SNPs to develop and implement comprehensive individualized care plans for enrollees. However, as CMS continues to build pathways to move dually eligible enrollees into D-SNPs, we urge the agency to proceed with caution and ensure appropriate oversight and coordination of benefits. It is imperative that D-SNP enrollees maintain the same access to Medicare-covered services as traditional Medicare enrollees and that beneficiaries retain the ability to choose the Medicare coverage options that best meet their individual needs.

[16] https://atiadvisory.com/wp-content/uploads/2022/02/Profile-of-the-California-Medicare-Population.pdf

Thank you for your consideration of our comments. If you have any questions, please contact me at mmillerick@calhospital.org or (771) 224-7224, or Megan Howard, vice president, federal policy, at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/

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