

Washington, D.C. Office

800 10th Street, N.W. Two CityCenter, Suite 400 Washington, DC 20001-4956 (202) 638-1100

January 27, 2025

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 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 our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners — including more than 270,000 affiliated physicians, two million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for policy and technical changes to the Medicare Advantage (MA) and Part D programs in contract year (CY) 2026.

The proposed rule includes important protections for MA beneficiaries and clarifications for Medicare Advantage Organizations (MAOs) that will improve how coverage works for enrollees, promote more timely access to care, strengthen behavioral health provider networks, help patients understand their Medicare coverage options and reduce the administrative burden of health plan requirements on health care providers. The AHA supports the proposed changes intended to strengthen consumer protections and oversight of MAOs, and we encourage the agency to finalize these important program updates.

INTERNAL COVERAGE CRITERIA

As CMS established in both the CY 2024 MA final rule and subsequent frequently asked questions (FAQs), MA plans may only utilize internal criteria when Traditional Medicare coverage rules are not fully established, meaning when additional, unspecified criteria are needed for the plan to interpret or supplement general provisions to determine



Acting Administrator Jeff Wu January 27, 2025 Page 2 of 13

medical necessity consistently. In these limited circumstances, CMS permits that "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature, as permitted in §422.101(b)(6)." Despite these seemingly straightforward requirements, our members report MAO utilization of internal coverage criteria that are inconsistent with or exceed CMS requirements and are not sufficiently transparent, and, as a result, serve as inappropriate obstacles to proper patient care. For example, one hospital shared an experience with a large national plan that denied an inpatient admission for a patient who satisfied the two-midnight criteria and whose care ultimately spanned beyond two midnights. The plan indicated that inpatient coverage was denied because the patient did not meet its criteria for inpatient acute level of care, suggesting that the plan applied additional medical necessity criteria beyond the admitting clinician's expectation that the patient would require inpatient level care extending beyond two midnights. Additionally, it remained unclear what criteria were used to make that determination or how they were applied to this specific patient's case. Because of examples like this, which are not unique, the AHA supports further actions to align MAO coverage with that offered through the Traditional Medicare program.

Definition of Internal Coverage Criteria

Citing common misunderstandings and misapplication of the coverage criteria provisions in the CY 2024 MA final rule and subsequent agency guidance, CMS proposes new regulatory text to explicitly clarify what the agency considers "internal coverage criteria." Specifically, CMS proposes to broadly 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 statutes, regulations, NCDs [National Coverage Determinations], LCDs [Local Coverage Determinations], or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination...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."

The AHA fully supports this straightforward, unambiguous definition of internal coverage criteria, which we hope will eliminate some MAOs' inappropriate use of proprietary criteria. Several AHA members have noted continued medical necessity denials that indicate a failure to meet the coverage requirements of large, third-party criteria sets (e.g. Interqual, MCG) without access to the criteria or indication that the criteria set was based on current evidence in widely used treatment guidelines or clinical literature, as required by § 422.101(b)(6). Instead, plan denials merely indicate that the proposed care failed to meet these commercial criteria set requirements. The proposed revisions would further clarify that denials like those described above are not permitted and establish that these third-party criteria are indeed subject to the important safeguards established in the regulation.

Acting Administrator Jeff Wu January 27, 2025 Page 3 of 13

Using Internal Coverage Criteria to Supplement or Interpret Plain Language CMS Criteria

CMS notes the NCDs and LCDs that MA plans must follow are developed as part of a rigorous process and the agency only believes that internal criteria would be needed in rare instances. The agency clarifies that internal coverage criteria may only be used to supplement or interpret the plain language of already existing content within the Medicare coverage and benefit rules — not to add new, unrelated coverage criteria for an item or service that already has existing, but not fully established, coverage policies. The AHA this clarification, which should limit plans' inappropriate internal criteria utilization. As noted above, our members continue to report widespread MA plan internal coverage criteria that are unrelated to or go substantially beyond the CMS standards, which interferes with patient access to care and creates disparities between MA and Traditional Medicare.

In addition to this proposed clarification, we encourage CMS to work to refine any NCDs and LCDs that plans are interpreting as unspecific or in need of supplemental information. Although we recognize that there may be instances in which plans may legitimately need to use internal criteria, their utilization intrinsically reduces parity of coverage across Medicare beneficiaries. As CMS notes in the rule, "internal coverage criteria are inherently "internal" to the MA plan that utilizes them...other MA plans are not required to use the criteria and therefore it would be an element of coverage specific to the MA plan." When MA plans utilize criteria not used by other plans or Traditional Medicare, they inevitably create coverage disparities across beneficiaries. To prioritize the goal of equitable access to care across beneficiaries, CMS should annually analyze MA plan internal coverage criteria to identify LCDs and NCDs that may need further clarification to eliminate the need for plans to utilize internal criteria. This would help ensure that all beneficiaries are receiving coverage under the same rules and that access to necessary care is not dependent on plan type.

Transparency and Public Accessibility

To ensure that providers and plan beneficiaries have access to an MA plan's specific coverage requirements, CMS proposes requiring MAOs to publicly display on their website a list of all items and services for which the organization uses internal coverage criteria when making medical necessity decisions. The posting would require the plan to include each specific criterion, a summary of the evidence used to support its use and appropriate sourcing information for the relevant evidence.

The AHA supports this provision, which builds upon transparency and increased accountability for plans established under the CY 2024 rule. Currently, a number of hospitals note that payer coverage criteria are either unavailable or merely reference a third-party medical necessity compendium, such as Interqual, making it difficult for providers to understand the specific information needed to ensure that a patient

Acting Administrator Jeff Wu January 27, 2025 Page 4 of 13

receives coverage for appropriate care. Perhaps more importantly, this requirement makes it much easier to enforce these regulations, as it would prevent internal medical necessity denials from being permitted absent the criterion being specifically referenced on the website. The AHA supports the November 2024 Medicare Data and Audit Proposed Protocol that established an annual collection of detailed MAO coverage criteria and evidentiary support. This provision supports that reporting requirement, providing clinicians with an efficient, referenceable database to determine whether medical necessity denials are based on properly disclosed criteria. Such increased transparency, when paired with robust enforcement efforts, will improve patient access to medically necessary care.

Prohibitions on Certain Internal Criteria

The proposed rule disallows MAOs from using certain coverage criteria unrelated to whether the patient's medical condition clinically justifies the associated service. Specifically, CMS prohibits plans from using internal criteria that do not provide clinical benefit to the patient and only exist to reduce the utilization of an item or service. Additionally, the regulation disallows plans from using clinical criteria that automatically deny coverage of a basic benefit without considering the individual patient's circumstances.

The AHA believes these proposals address a significant concern for many providers. Our members repeatedly indicate that some plan criteria seem disconnected from clinical decision-making, raising the question about the plan's motivation for using them. This is particularly true with automated criteria. For example, our members report certain payer artificial intelligence (AI) tools that predict the number of days an MA enrollee will need care in a post-acute care setting and terminate coverage of services beyond that number, irrespective of any individual patient's circumstances or the recommendation of the treating medical team. Prohibiting such inappropriate criteria should protect patients and ensure that MA beneficiaries can access the basic benefits they need, and to which they are entitled.

Elimination of Benefit Outweighing Harm Requirement

CMS proposes to eliminate the existing requirement at § 422.101(b)(6)(i)(A) that the MAO must demonstrate that an internal coverage criterion provides clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. CMS notes that this specific metric is difficult to prove through evidence and to enforce, explaining that plans have typically attempted to comply with this metric merely by showing how avoidance of the specifically requested treatment or service would eliminate potential risks with that treatment. Instead, CMS offers an alternative that requires the plan to display that the specific criteria support patient safety.

Acting Administrator Jeff Wu January 27, 2025 Page 5 of 13

The AHA understands the difficulties in enforcing the existing policy, though we note that plans' inability to comply may have more to do with their policies than CMS regulations. To ensure that MA beneficiaries do not have unnecessary obstacles to their care, we remain supportive of the requirements in 422.101(b)(6)(i)(A). MAOs should in a very judicious manner approach the creation of policies that have the potential to interfere with essential care, and we do not believe that adequately showing that a policy will not do more harm than it will cause is an unreasonable requirement. As we note above, we support CMS for establishing the prohibition on coverage criteria that exist merely to reduce the utilization of an item or service. In this same vein, plans should not be permitted to claim a relatively minor patient benefit if it comes at a cost of significantly reduced patient access to necessary treatment. We believe the rule establishes a necessary balance between permitting internal criteria while ensuring that they are not potentially detrimental to patient health — a protection we fear would be lost if this requirement were removed.

Furthermore, we do not believe the proposed solution requiring the plan to provide evidence that a criterion supports patient safety will yield better plan compliance. If MAOs were unable to clearly show that the clinical justification for a policy outweighs potential harms, they are likely to be similarly challenged in showing that the plan supports patient safety. A policy that inherently limits some beneficiary access to care must overcome such access concerns to support patient safety.

For these reasons, we recommend that CMS maintain its existing policy requiring plans to show that an internal coverage criterion provides clinical benefit that outweighs potential harm.

ORGANIZATIONAL DETERMINATIONS AND MEMBER APPEALS

The proposed rule includes provisions seeking to protect patient and provider appeal rights for adverse organizational determinations issued by MA plans. The AHA supports policies that work to preserve opportunities to appeal coverage rights and ensure plans provide access to necessary basic benefits.

Clarifying Liability Cannot Be Determined Until Payment Determination Is Made

CMS reasserts that a patient's liability for payment cannot be determined until the provider files a claim for services. Thereby, CMS is preventing plans from denying appeal rights for coverage determinations by implying it is a payment matter and will not impact the patient's ultimate liability. **The AHA appreciates that the administration recommends this clarification, which would ensure that patients have the right to challenge plan coverage determinations made prior to the filing of a claim.** As CMS notes, many MAOs have attempted to classify denials of coverage as "payment disputes" or assert that the decision will not impact the final bill. Such preemptive determinations can prevent patients from having appropriate access to appeals and jeopardize access to post-acute care. We believe this added protection is important to

Acting Administrator Jeff Wu January 27, 2025 Page 6 of 13

ensure that patients and their providers can establish and obtain MA coverage that meets the patient's care needs.

In addition to the above clarification, we recommend that CMS explicitly note that financial liability cannot be determined until a claim is processed. The proposed regulation uses the phrase "requests" and "payment decisions." While it seems clear that CMS intended this to include claims, historic plan misinterpretation of guidance warrants the specific inclusion of the term "claim" within the regulation.

Modifying the Definition of "Organization Determination"

The proposed rule establishes that an organizational determination is a decision regarding the availability of patient benefits and is not limited to a specific point in the patient's treatment. Specifically, CMS clarifies that an organizational determination is a decision "regarding the benefits an enrollee is entitled to receive under an MA plan . . . and the amount, if any, that the enrollee is required to pay for a health service... An organization determination may be made prior to the receipt of services (for example, prior authorization), after the receipt of services (for example, payment requests), or during receipt of services (for example, continuation or termination of services) the enrollee receives from either contracted or non-contracted providers."

AHA supports this clarification, which addresses two specific issues our members report when interacting with MA plans. First, the proposed rule reiterates that a decision to lower the level of care at which coverage will be paid is an organizational determination. Hospitals have repeatedly reported plan attempts to falsely categorize the level of care determinations as payment issues rather than organizational determinations, which the plans assert makes them fall outside of the CMS regulations. Secondly, CMS indicates that concurrent reviews are considered organizational determinations. This clarification is very important to protect the provider's appropriate application of the two-midnight rule requirements. Plans engaged in concurrent review frequently reassess whether a patient's care should be classified as inpatient or observation, using information gathered long after the admitting clinician issued the order to admit. Additionally, as the rule notes, this often occurs after the plan has issued a medical necessity determination by approving the authorization request to admit the patient. By re-establishing that concurrent reviews are organizational determinations, provider admissions should not be rescinded by plans second-guessing previously authorized admissions, and any decisions regarding continued inpatient status would be subject to notice and appeal requirements.

Provider Notice of Organization Determination when Provider Is Acting on Behalf of a Patient

The AHA supports CMS' efforts to ensure that providers who submit appeals on behalf of their patients receive necessary information about the coverage decision from the plan. CMS notes that existing rules only require plans to notify the patient when issuing

Acting Administrator Jeff Wu January 27, 2025 Page 7 of 13

an organizational determination on a standard (non-expedited) request, despite requirements that the submitting provider receive decision information for expedited requests. CMS indicates that they see no reason to omit the provider from standard determinations, and we agree. As the rule notes, providers are often in the best position to properly interpret and explain medical determinations to patients. Furthermore, patients are likely to assume that their provider would receive the response to an appeal that the provider filed for them. As a result, sharing information with the provider has a high likelihood of helping patients better understand their coverage and their rights with regard to the plan determination, and we support protecting such provider information access.

Automatic Appealable Organization Determination if Plan Fails to Respond

In the proposed rule, CMS notes that if an MAO fails to provide the enrollee, physician or provider involved with timely notice of an organization determination, this failure itself constitutes an adverse organization determination and may be appealed. We appreciate the agency establishing this useful appeal right for patients and for extending it to the provider. However, to protect timely access to necessary treatment, we encourage CMS to consider all treatment requests for which a plan fails to issue a timely decision to be considered automatically approved. This would prevent plans from intentionally delaying decision-making to prevent patients from receiving prospective treatment.

Under the Interoperability and Prior Authorization final rule, MAOs are permitted up to 72 hours for expedited and seven days for standard authorization requests. Current CMS policy indicates that when a plan fails to respond within these timeframes, the provider and/or patient must engage in the appeals process. The process to appeal an adverse determination — even if ultimately successful — can generate delays that impact patient care. To start, an initial prior authorization approval can take at least 72 hours in the best-case scenario. Due to the high rate of denials, however, many beneficiaries will wait an additional 72 hours or more — sometimes weeks — for the peer-to-peer and appeals processes to occur. For some patients, such as those awaiting authorization for post-acute care, this additional wait time leaves them stuck in settings that are not equipped to care for their unique rehabilitative needs and can be a material detriment to patients' long-term outcomes.

To cut down on unnecessary delays in patient care, we recommend that authorization requests to which the plan fails to respond are simply considered approved, which would allow the patient to receive timely care and prevent them from experiencing the numerous steps of a plan appeal.

COST-SHARING LIMITS FOR BEHAVIORAL HEALTH SERVICES

As part of its larger strategy to improve access to behavioral health services under Medicare programs, CMS proposes to align in-network cost-sharing for behavioral health service categories between MA and Cost Plans with that under Traditional

Acting Administrator Jeff Wu January 27, 2025 Page 8 of 13

Medicare. Specifically, the agency would amend 42 CFR §§ 417.454 and 422.100 to require in-network cost-sharing for these services to be no greater than that of Traditional Medicare for MA and Cost Plans, including Employer Group Waiver Plans. Coupled with proposals for plans to meet more rigorous network adequacy standards, this proposal would significantly reduce barriers to access to care for MA enrollees.

As background, enrollees in Traditional Medicare pay 20% coinsurance for most treatments, with zero cost sharing for opioid treatment services; however, enrollees in MA plans may be charged up to 50% coinsurance for the same services. In the proposed rule, CMS provides analysis that shows that about one-guarter of MAOs charge in-network cost-sharing amounts that are greater than Traditional Medicare for mental health specialty, psychiatric and partial hospitalization program (PHP) services, while up to 71% of plans charge higher amounts for outpatient substance use disorder (SUD) services. Considering that about one in four Medicare beneficiaries has a mental illness, the magnitude of these discrepancies is enormous. The AHA supports CMS for taking this straightforward approach to not only improving access to behavioral health services for MA enrollees but also striving for equitable coverage across different types of coverage. In particular, we appreciate that CMS would specifically add mental health specialty, psychiatric, PHP, intensive outpatient programs, inpatient hospital psychiatric services (all length-of-stay scenarios). outpatient SUD and opioid treatment program services to the enumerated services under this policy in the CFR. By listing these detailed services and programs, the agency can fill common gaps in coverage that individuals may be unaware of when they enroll in an MA plan.

In addition, CMS solicits comments on whether the agency should apply these proposed changes to the behavioral health cost-sharing standards beginning in CY 2026 or CY 2027 and whether there should be a transition period from the existing CY 2025 standards for select service categories. **The AHA recommends that CMS apply these changes beginning Jan. 1, 2026, as proposed.** The existing regulations under Traditional Medicare are comparatively simple and easy to understand, while there exists an enormous amount of variation in cost-sharing policies under MA plans; indeed, given that almost three-quarters of MA beneficiaries enroll in plans with \$0 premiums, unexpected and variable cost-sharing requirements result in unpredictable shifts in spending.¹ Reducing this variation may in effect improve the accuracy of estimated MA rates and thus reduce overpayments.

Further, from an aggregate perspective, this proposal will not result in meaningful losses for MAOs compared to what is allowed under current rules. When submitting bids to CMS to estimate the cost of providing services under their plans, MA issuers are

^{1.} MedPAC. (2024). "The Medicare Advantage Program: Status Report." Report to the Congress: Medicare Payment Policy. Accessed 4/27/24, https://www.medpac.gov/document/chapter-12-the-medicare-advantage-program-status-report-march-2024-report/.

Acting Administrator Jeff Wu January 27, 2025 Page 9 of 13

already required to show that the overall cost of their plan (including all benefits and cost-sharing elements) must be "actuarily equivalent," or roughly equal to the cost under Traditional Medicare. While plans can modify details of the plan design to achieve this balance (e.g., offering more generous coverage in some areas while limiting coverage in others), this rule would simply ensure that cost-sharing requirements for behavioral health services specifically are not subject to these modifications. Explicitly aligning the cost-sharing requirements between MA and Traditional Medicare for behavioral health services would help fill a common gap in coverage that negatively affects millions of enrollees.

ENSURING EQUITABLE ACCESS TO MA SERVICES — GUARDRAILS FOR AI

The CY 2026 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 does not cover any significant new ground but rather seeks to clarify prior rules to ensure that MAOs continue providing equitable access to services, irrespective of technological advances, by updating existing regulations to account for the use of AI and other automated systems.

In a February 2024 Health Plan Management System memo, CMS established that "an algorithm, artificial intelligence, or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MAOs are made." We appreciate CMS using the CY 2026 update to clarify the definition of "automated system" to reflect the broad application of these technologies within MA plans to include "any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both."

Further, we appreciate that CMS added flexibility in the definition of automated systems by not limiting the definition to specific types or current uses of AI, and includes "systems derived from machine learning, statistics, or other data processing or artificial intelligence techniques." Additionally, in a statement that aligns with the Health Data, Technology and Interoperability Rule requirement for algorithmic transparency, CMS asserts that an MAO is responsible for any internal coverage criteria built into an automated system and that the specific details of that criteria used in any automated tools must be publicly accessible and meet current CMS evidentiary standards at § 422.101(b)(6).

MEDICAL LOSS RATIO

To improve medical loss ratio (MLR) reporting and oversight and ensure that patient premiums are spent in accordance with legislative intent, CMS proposes to make several changes to the MLR requirements for MA plans. The AHA is supportive of the

Acting Administrator Jeff Wu January 27, 2025 Page 10 of 13

agency's focus on the MLR. The MLR standard is an important tool to ensure sufficient resources are dedicated to paying for covered medical services and ensuring patient access to care, while also holding health plans accountable for how premium dollars are spent. In recent years, we have been increasingly concerned that the MAO-reported ratios are inconsistent with provider and patient experience. Therefore, we believe increased attention to the MLR is essential to protect beneficiaries and ensure that the administration's finite resources are spent properly.

Additional Data Collection

CMS proposes to increase the information that plans must report each year regarding their MLR calculations. Although previously required to submit detailed information on how the plan reached its reported MLR figure, inclusive of information necessary to validate that amount, CMS reduced reporting requirements in 2019, requiring only the organization name, contract number, adjusted MLR, and the remittance amount. This ultimately curtailed the agency's ability to conduct oversight. For the MLR to adequately protect patient premium dollars and the administration's health care expenditures, the AHA supports CMS' reinstatement of earlier reporting requirements.

Requiring Clinical or Quality Improvement Standards for Provider Incentive and Bonus Arrangements Included in MLR Numerator

CMS cites inconsistent methods for insurer determinations of which expenses can be included as a quality improvement activity (QIA) in the MLR numerator. Including additional or inappropriate expenses in the MLR numerator can artificially inflate the plan's MLR. This allows the plan to more easily meet the MLR standard while undermining the purpose of the MLR, which is to incentivize plans to reduce administrative costs and decrease funding for activities such as marketing and other business functions that do not explicitly provide value for taxpayers and beneficiaries.

To standardize the activities that can be included as a QIA in the MLR numerator, the rule seeks to align Medicare MLR reporting with commercial and Medicaid MLR rules by clarifying that only expenses directly related to activities that improve health care quality can be included as QIAs in an MLR numerator. In addition, to ensure that reported provider bonus payments are properly based on QIAs, the rule proposes that only those provider incentives and bonuses tied to clearly defined, objectively measurable and well-documented clinical or quality improvement standards may be included in the MLR numerator for MA and Part D contract MLR calculations.

The AHA supports CMS efforts to ensure that quality improvement payments are adequately grounded in legitimate activities, particularly since we have heard reports of plan misclassification of expenses, such as utilization management activities (as we noted in <u>our response</u> to the 2022 MA programmatic request for information), in the MLR numerator.

Acting Administrator Jeff Wu January 27, 2025 Page 11 of 13

MLR Audits

To improve the accuracy of MLR reporting and ensure that MA plans and Part D sponsors are appropriately spending funds to provide care to enrollees, the rule proposes to create an MA and Part D MLR audit process. The audit program would be designed to inspect and analyze a plan's MLR submissions and include specific compliance actions that the agency can use, where appropriate, to address plan noncompliance with MLR requirements.

The AHA supports the proposal of this important enforcement mechanism. As the agency states, the growth of the MA and Part D programs requires greater scrutiny to ensure that MAOs and Part D sponsors are appropriately spending funds to provide care to enrollees. We encourage the administration to utilize its full spectrum of corrective actions to ensure compliant plan behavior, including corrective action plans, fines and intermediate sanctions. Additionally, we support making MLR audit enforcement activities public and identifiable. This information is important for both providers and patients as they determine contractual status and participation in an MA plan.

PROVIDER DIRECTORY INFORMATION

CMS proposes to require MA plans to report provider directory data to CMS for incorporation into the agency's Medicare Plan Finder platform — an online resource designed to aid enrollees in selecting Medicare coverage. Furthermore, the rule would require MA plans to attest to the accuracy of provider directory information.

The AHA supports making benefits information easier to access and understand for prospective plan beneficiaries. To ensure that our seniors receive plans that adequately meet their needs, CMS should make researching plans as simple as possible. We believe that by incorporating provider directory data into Medicare Plan Finder, patients will have an easier time cross-comparing potential MA plans.

In this rule, CMS is considering requiring a yearly attestation as to the accuracy of provider directory information. We would support this cadence, but caution against more frequent attestations, which may require plans to conduct excessive credentialing and provider information-gathering protocols and could bog down provider offices. Furthermore, we encourage CMS to work to streamline the information that each plan needs for certifying that a provider is in a plan network and can be included in the plan's directory. Variance in each plan's data collection protocol creates idiosyncrasies that contribute to administrative burdens for providers.

ENFORCEMENT

As detailed in our November 2024 <u>response</u> to the Medicare Part C Utilization Management Annual Data Submission and Audit Protocol, we believe robust

Acting Administrator Jeff Wu January 27, 2025 Page 12 of 13

enforcement of existing rules is imperative. Without a steadfast commitment to enforcement, we are concerned that beneficiaries will suffer from plans' failure to comply with these important rules. Indeed, look no further than the ongoing difficulties with MAOs' use of internal coverage criteria. As CMS issues clarifications and other recommendations in this proposed rule, the agency often cites plan confusion as the justification for creating the policy. We are skeptical since violations have continued despite clear requirements indicated in CMS plan contractual policy, the CY2024 final rule, the CY2025 final rule, the 2025 FAQs clarifying ambiguities, and the Department of Health and Human Services Office of the Inspector General (HHS-OIG) report (and corresponding CMS acknowledgment) of plan noncompliance with federal regulations. The AHA believes that certain plans are unlikely to change their practices until meaningful enforcement and penalties are routinely implemented. We encourage the administration to consider the following areas as part of their oversight and enforcement activities.

Data Collection and Reporting on Plan Performance

There are currently limited data reporting mechanisms that provide CMS with information about plan-level coverage denials, appeals and grievances, and delays in care resulting from plan administrative processes. These are important indicators of 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. HHS-OIG recommended in 2014 that CMS identify whether outlier data values reflect inaccurate reporting or atypical performance, and use reporting requirements data as part of its reviews of MAOs' performance. We believe this could be a useful approach to conducting data-driven enforcement activity and are encouraged by CMS' discussion in recent MA rulemaking of expanding the reporting requirements for MA plans related to the access-indicator metrics discussed above.

In addition, we recommend that existing MA plan data, which are submitted to CMS annually and must be audited by an outside organization, be used to a greater extent to guide oversight and enforcement activities. It appears that CMS uses MA plan determination data in a relatively limited manner, as the determination data are not used in star ratings and there is no documentation to suggest that this specific data drives oversight decisions such as identifying which MA plans to audit. 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 plans, and/or incorporating organization determination data into star ratings.

Enforcement Penalties

Acting Administrator Jeff Wu January 27, 2025 Page 13 of 13

Penalties are a necessary part of enforcement to incentivize compliance with CMS rules. CMS' acknowledgment in the 2024 MA final rule that many of the included provisions are restatements of existing CMS policy shows that rules alone are insufficient to achieve compliance, and that enforcement is critical to ensuring meaningful change. We support CMS exercising 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, we recommend that CMS impose intermediate sanctions (e.g., suspension of marketing and enrollment activities) and civil monetary penalties — or terminate the contract in cases where a plan does not make good faith efforts to comply. Each of these elements will be critical to ensuring these important changes become standard operating procedures for MA plans and have the intended effects on beneficiary protection and access to care.

We also want to acknowledge in our advocacy for greater enforcement activity that we recognize not all MA plans are the same; many have active partnerships with providers in service of their shared patients/members and consistently act in good faith to follow the rules. To this end, we believe that enforcement actions should be targeted at MA plans that have 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 investigation. 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.

We thank you for the opportunity to comment on these important topics. Please contact me if you have any questions, or feel free to have a member of your team contact Terrence Cunningham, AHA's senior director for administrative simplification policy, at tcunningham@aha.org.

Sincerely.

/s/

Ashley Thompson Senior Vice President Public Policy Analysis and Development