

Jan. 5, 2024

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services 7500 Security Blvd. Baltimore, MD 21244

RE: CMS 4205-P, Medicare Program; Contract Year 2025 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; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure:

On behalf of its member hospitals, the Michigan Health & Hospital Association (MHA) appreciates this opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the above referenced proposed rule for calendar year (CY) 2025. We believe this rule will have positive changes on Michigan hospitals and the Medicare Advantage (MA) beneficiaries they care for. Currently, 60% of Michigan's Medicare enrollees are enrolled in an MA plan, ranging from 42 to 75% at the county level. The MHA is supportive of the attached comments prepared by the American Hospital Association (AHA). Specifically, we want to highlight:

- Enforcement and Compliance of CMS Rules The MHA remains concerned about MA plan compliance with the 2024 MA final rules which took effect Jan. 1. We urge the CMS to conduct rigorous monitoring and enforcement of the new rules including plan-level data collection and reporting, regular auditing, pathways for stakeholders to report suspected violations and penalties for non-compliance. Enforcement is critical for ensuring meaningful change given the CMS' acknowledgement in the final rule that many of the included provisions are restatements of existing CMS policy. We urge the CMS to hold plans accountable for complying with the rule and recommend that the CMS impose intermediate sanctions, civil monetary penalties or terminate contracts of noncompliant plans.
- <u>340B Underpayments</u> We urge the CMS to use this rulemaking to address concerns outlined by the AHA and others in comments regarding the proposed remedy with respect to MA plans and urge the CMS to make hospitals whole for 340B underpayments from MA plans between 2018 and 2022. We urge the HHS to take all possible measures within the agency's authority to ensure MA plan compliance with repayment and that hospitals are made whole for these underpayments.

The MHA also has significant concerns about the impact of the recoupment policy finalized in November that will reduce traditional Medicare outpatient prospective payment system rates by 0.5% annually over 16 years, starting in 2026. The HHS failed to include a corresponding requirement for MA plans to pass the savings from the recoupment (which would accrue to MA plans that apply the 0.5% payment reduction) to hospitals whose 340B payments were cut by MA plans between 2018-2022. This could double the adverse impact of the recoupment on hospitals as many hospitals:

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- Experienced the same 340B payment reduction in MA as they did under Traditional Medicare between 2018 and 2022
- Have not been repaid or made whole for their losses under MA between 2018 and 2022 because of the HHS' unlawful 340B payment policy
- Will be subject to further OPPS payment reductions starting in 2026 if MA plans adopt the recoupment reduction consistent with traditional Medicare payment rates.
- Increased Data Collection and Reporting The MHA urges the CMS to require MA plans to submit encounter data which would allow the CMS to have data for the MA population similar to claims level data available for the traditional Medicare population. This is vital for helping hospitals model and understand the estimated impact of Medicare proposed and final rules annually since MA plans are required to pay Medicare FFS rates in the absence of a contract. This is becoming increasingly important as a growing number of enrollees choose MA plans.

We believe the proposed changes will have a positive impact on the Medicare Advantage enrollees, hospitals and other providers. Please contact me at <u>vkunz@mha.org</u> with any questions.

Sincerely,

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Dear Administrator Brooks-LaSure:

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) program in contract year (CY) 2025.

INCREASED DATA COLLECTION AND REPORTING FOR PARTS C AND D

In the proposed rule, CMS affirms its authority to collect detailed information from MA plans under current regulations and proposes to lay the groundwork for new data collection to be established through the Paperwork Reduction Act process, which includes advance notice and public comment periods. We strongly support additional data collection and reporting on plan performance metrics that are meaningful indicators of patient access, including the specific examples CMS provides in the preamble, such as service level data for all initial coverage decisions and plan level appeals; decision rationales for items, services or diagnosis codes; and other possible data to provide CMS greater transparency on MA plan utilization management and prior authorization practices. The AHA has consistently advocated for greater data collection and reporting on plan-level coverage denials, appeals and grievances, as well as delays in care resulting from plan administrative processes, and believes additional data collection in



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these areas is critical to inform CMS oversight and enforcement activities. Our more detailed recommendations on data collection and reporting are summarized in the subsequent section on enforcement activities below. With this in mind, the AHA strongly supports CMS' direction with respect to augmenting data collection, reporting and transparency in the Part C program and looks forward to engaging on future rulemaking on this topic.

ENROLLEES' RIGHT TO APPEAL AN MA PLAN DECISION TO TERMINATE COVERAGE FOR NON-HOSPITAL PROVIDER SERVICES (§ 422.6)

CMS is proposing to align the appeal rights of MA beneficiaries more closely with the rights afforded to Traditional Medicare beneficiaries when coverage is being terminated for home health agency (HHA), skilled nursing facility (SNF) and comprehensive outpatient rehabilitation facility (CORF) care. **AHA strongly supports these proposed revisions and encourages CMS to finalize them.**

Traditional Medicare and MA enrollees both have expedited, or fast track, appeal options if the patient disagrees with a determination that services are no longer needed. Under both MA and Traditional Medicare, beneficiaries maintain the right to have their timely appeal of termination of HHA, SNF or CORF services heard by a Quality Improvement Organization (QIO).¹ In Traditional Medicare, even if the appeal is not filed in a timely manner, the QIO must still review and issue a decision on the appeal. However, in MA, if the beneficiary fails to meet the required deadline for appeal to the QIO, the untimely appeal is then heard by the MA plan rather than the QIO. In addition, under MA, if the beneficiary leaves the facility or otherwise ends services, they forfeit their right to appeal.

CMS has proposed to modify its regulations so that untimely appeals by MA beneficiaries (those which miss the appeal deadline) would now be heard by the QIO, instead of the MA plan, consistent with the procedure under Traditional Medicare. In addition, CMS is proposing to eliminate the clause that forfeits the ability of an MA beneficiary to have an appeal heard if they leave the facility or otherwise terminate services.

AHA applauds CMS for this proposal to align MA and Traditional Medicare appeal rights more closely and ensure appropriate access to care for MA beneficiaries. AHA, alongside a chorus of other stakeholders and government agencies, has urged CMS in recent years to address disparities in access to care for MA beneficiaries, including post-acute care services. The CY 2024 MA final rule took important steps to address many of these issues, and we believe creating uniformity in appeal rights for

¹ In the case of MA, the QIO is contracted as the Independent Review Entity required to hear timely reviews at 42 C.F.R. § 422.626.

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Medicare beneficiaries when HHA, SNF or CORF services are terminated would be a further beneficial step in creating parity between MA and Traditional Medicare as well as ensuring appropriate consumer protections.

In addition, we support CMS' provision to eliminate current rules that require automatic forfeiture of appeal rights for MA enrollees upon leaving a facility or ending services. There are many complicated steps involved in fighting an inappropriate termination of services, and patients can be faced with an unknown financial liability if their insurer refuses to pay for their care, prompting some patients to leave a facility or otherwise discontinue services before they are medically ready. This is an impossible situation for many patients and families when their medical team has indicated it is not safe for the patient to be discharged home yet (or home without HHA services), but the patient's insurer has indicated they will not continue paying for covered services in a facility or provide support at home through an HHA. Patients should not be penalized in these circumstances and should maintain access to their full set of appeal rights whether they opted to remain or not in a post-acute care facility when faced with a coverage termination notice from their insurer. This is especially important given reports from the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) highlighting "high overturn rates of appealed denials, and widespread and persistent CMS audit findings about inappropriate denials. [which] raise concerns that some Medicare Advantage beneficiaries and providers were denied services and payments that should have been provided."² Accordingly, we strongly support CMS' proposed updates to strengthen member appeal rights and ensure that patients do not forfeit certain rights in the wake of an insurer termination of services.

Lastly, we encourage CMS to consider applying the same protections and appeal rights described above more broadly than HHA, SNF and CORFs, and extend these protections to hospital provider types including short-term acute, inpatient rehabilitation and long-term care hospitals. The same rationale for the above provisions for non-hospital providers also applies for appeals of inpatient hospital services. Specifically, both Traditional Medicare and MA beneficiaries have a right to appeal to a QIO when a hospital or MA plan, respectively, determine that inpatient hospital care is no longer necessary.³ However, while a Traditional Medicare beneficiary can have a QIO review an untimely appeal, an MA beneficiary who has their hospital services terminated by the MA plan can only have the untimely appeal heard by the MA plan.^{4,5} This is the specific issue that CMS seeks to correct in creating parity in appeal rights between Traditional Medicare and MA for SNF, HHA and CORF services, and we believe the same rationale would apply to inpatient hospital services, including short-term acute, inpatient rehabilitation and long-term care hospital care. **Therefore, AHA encourages CMS to**

² <u>https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf</u>

³ 42 C.F.R. § 405.1206; 42 C.F.R. § 422.622

⁴ 42 C.F.R. § 405.1206(b)(6)

⁵ 42 C.F.R. § 422.622(b)(5)

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take an analogous step for appealing terminations of inpatient hospital services to ensure MA beneficiaries have the same appeal rights as Traditional Medicare beneficiaries where coverage of inpatient hospital care is terminated by an MA plan. Specifically, AHA recommends that CMS modify its regulations to ensure that QIOs also review untimely appeals of MA notices of termination of coverage of inpatient hospital services.

IMPROVING ACCESS TO BEHAVIORAL HEALTH CARE PROVIDERS

The AHA applauds CMS' attention to gaps in access to behavioral health services, including its consideration of more rigorous network adequacy standards as one tool to improve MA patients' access to these critical services. Coupled with other efforts — notably those to increase the behavioral health workforce — stronger network adequacy standards likely will reduce the volume of delays and denials for behavioral health care coverage under MA.

We support CMS' proposal to add a range of behavioral health providers under a category of "Outpatient Behavioral Health" as a facility specialty for which CMS sets MA plan network adequacy standards. Specifically, this proposal would include marriage and family therapists (MFTs), mental health counselors (MHCs), Opioid Treatment Program providers, Community Mental Health Centers, addiction medicine physicians, and others who furnish addiction medicine and behavioral health counseling or therapy as specialty types for which there are specific minimum network standards. These would be in addition to the current requirements to demonstrate adequate contracts with psychiatry and inpatient psychiatric facilities. This proposal is consistent with other recent rulemaking, specifically the calendar year 2024 Physician Fee Schedule final rule and FY 2024 Outpatient Prospective Payment System final rule, which establish new coverage and payment provisions for MFTs and MHCs. Further, in the CY 2024 final rule on Policy and Technical Changes to the MA Plan Program, CMS added clinical psychologists, licensed clinical social workers and prescribers of medication for opioid use disorder to the types of practitioners to be included in network adequacy standards. Behavioral health care services involve a wide continuum of providers, facilities and settings that cannot necessarily be substituted one for the other and sufficiently meet patient and community needs. Hence, these proposals would, if finalized, help ensure access to a more comprehensive spectrum of medically necessary behavioral health care and provide CMS with more detailed information to evaluate whether MA plans are meeting the precise needs of their beneficiaries.

The AHA urges caution, however, with the agency's proposal for the additional facility specialty to be eligible to count as part of the 10% "credit" towards meeting time and distance standards when offering telehealth services. CMS should apply similar capacity standards to telehealth providers as is done with in-person providers — that is, to consider a provider to be part of the network, that provider must be accepting new patients and offer specified services within a certain number of days. Without caution,

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this credit method runs the risk of allowing issuers to dilute their market with virtual providers who may not actually have the ability to take on patients while simultaneously reducing their in-person footprint.

Finally, we recognize the substantial challenge these proposals may pose to plans given the inadequate nature of the behavioral health workforce. In some communities, plans may not be able to meet these heightened standards in 2025. While we believe it is still important to finalize these proposals, as we expect they will contribute to a more favorable environment for behavioral health care providers to participate in plan networks, we urge CMS to develop mechanisms to waive or otherwise make exceptions to these rules in markets where plans acting in good faith still cannot contract with the full spectrum of providers.

UTILIZATION MANAGEMENT COMMITTEES AND HEALTH EQUITY ANALYSIS

CMS proposes to require MA plans to conduct an annual health equity analysis of utilization management (UM) policies through the newly established UM committees, which were created by the CY 2024 MA final rule. The UM committees are internal committees convened by health plans that are responsible for reviewing annually all utilization management policies, including prior authorization, and ensuring policies and procedures are consistent with Medicare coverage requirements. Specifically, the proposed rule would require MA UM committees to: (1) have a committee member with expertise in health equity, (2) conduct an annual health equity analysis of prior authorization policies and procedures used by the plan, and (3) make the results of the analysis publicly available on their website.

The AHA supports CMS' efforts to ensure that MA plans meet the access needs of underserved populations, who may be disproportionately impacted by prior authorization policies that have the potential to create additional barriers to care. Half of all Medicare-eligible beneficiaries are now receiving coverage through an MA plan, and enrollees from historically marginalized communities account for a disproportionate share of overall MA enrollment. According to a 2023 Kaiser Family Foundation analysis, "Medicare Advantage enrollees were more likely to be Black or Hispanic, have incomes below \$20,000 per person, live in urban areas, and have lower levels of education" than those in Traditional Medicare.⁶ With this in mind, it is especially critical to ensure that UM programs and other MA plan business practices do not create barriers for patients that could contribute to inequities in access to care or health outcomes. At the same time, we recognize that an analysis of UM practices alone may not be sufficient to

⁶ <u>https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/#:~:text=Compared%20to%20traditional%20Medicare%20beneficiaries%20in%202021%2C %20Medicare%20Advantage%20enrollees,3%2C%20Appendix%20Table%201</u>

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identify gaps in health equity due to unmet need, and we encourage CMS to continue advancing broader policy efforts to advance health equity goals. We also encourage CMS to take additional steps to strengthen the role of the UM committees and conduct sufficient oversight to ensure meaningful review of policies with active engagement from contracted providers. Our specific recommendations include:

- Expanding the duties of the UM committees to include oversight of all internal coverage criteria used by the MA plan in addition to UM policies.
- Requiring that applicable UM policies and procedures are developed in consultation with contracted providers, including requiring a seat on the UM committee be filled by a clinician from a contracted provider organization.
- Requiring that the UM committee include representation from specific types of providers with expertise in relevant medical disciplines with a history of inappropriate denials, such as behavioral health and rehabilitation services.
- Requiring that the UM committee solicit input from enrollees, including enrollees from historically marginalized communities, on the development of UM policies and their impact on patient access to care.
- Requiring that the UM committee have an active and ongoing role throughout the year as opposed to only reviewing policies on an annual basis.
- Mandating that UM committee reports and findings be publicly available, or at a minimum, available upon request to enrollees and contracted providers.
- Conducting regular audits of UM committee activities, such as quarterly or biannual reviews, to ensure that plan policies are clinically valid and adequately reviewed with appropriate oversight. CMS may also want to consider the effects of UM committee findings or deliberations on the rate and validity of organizational determinations to determine if the presence of a UM committee is improving patient access to care as intended.

DATA INTEGRITY FOR APPEAL MEASURES AND STAR RATING CALCULATION

The AHA appreciates the agency's proposals to ensure the completeness and accuracy of complaint and appeals data reported to CMS contractors and used in the calculation of MA plan star ratings. Specifically, CMS proposes to ensure that MA plans are adequately sending all partially favorable or unfavorable reconsideration data to Independent Review Entities (IREs), in accordance with Part C appeals protocol and corresponding star ratings metrics. The rule would require that plans failing to submit complete and total data to the IRE automatically receive a 1-star rating for measures scoring the MA plan's timely review and consideration of appeals. The AHA strongly supports this proposal, which would help to make certain that CMS has the information necessary to ensure that plans are appropriately considering appeals and that MA enrollees receive timely and appropriate access to medically necessary services under the Medicare program.

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AHA members have reported concerns with how certain MA plans handle member appeals in a manner that appears designed to shield denials from IRE review and CMS oversight, which underscores the importance of the proposed provisions for consumer protection and insurer accountability. For example, members have shared examples with us of several large national MA plans unilaterally deeming member appeals invalid or converting medical necessity appeals filed on behalf of patients into provider disputes, thereby circumventing plan obligations to report these appeals to CMS and blocking IRE access to essential data on plan appeals that impact the calculation of plan star ratings.

Additionally, certain MA plans are consistently failing to issue the required Notice of Dismissal to parties requesting reconsideration, despite clear CMS rules requiring them to do so. Instead, a plan unilaterally determining that an appeal is invalid or converting a member appeal to a provider dispute evades public reporting requirements, making member appeals invisible to CMS and its contractors — and ensuring a subset of member appeals do not count against a plan for the purpose of its star rating calculation. This inappropriately skews MA plan star ratings on appeals measures, which we believe leads to most of the largest national plans receiving star ratings scores of 97-100%, despite potential inaccuracies or omissions in the data being used to calculate these measures. More importantly, these plan processes collectively deprive MA enrollees from exercising the regulatory protections available to them under federal rules, which are designed to ensure access to medically necessary care and equity with services that would be covered under Traditional Medicare. As a result, the AHA urges CMS to finalize these proposed revisions and encourages the agency to monitor plan compliance with the reporting of appeals measures to ensure accurate reporting and calculation of star ratings for these important measures.

NEW GUARDRAILS FOR PLAN COMPENSATION TO AGENTS AND BROKERS

CMS proposes new guardrails for plan compensation to agents and brokers in response to the agency's concerns about consumers being steered to plans that may benefit an agent or broker financially but may not be the best option to meet the beneficiary's coverage needs. We strongly support CMS' efforts to advance consumer protections and ensure that seniors have access to accurate and complete information about their Medicare options to enable informed decision-making about coverage.

Hospitals and health systems nationwide regularly encounter Medicare beneficiaries who do not understand their coverage or benefits or who may have been enrolled in an MA plan without fully appreciating their options or the potential implications of opting out of Traditional Medicare coverage. We also have heard from some members that they occasionally work with patients who report being unaware that their coverage was switched from Traditional Medicare to coverage through a private MA plan and believe this was done without their consent. Administrator Brooks-LaSure January 5, 2024 Page 8 of 14

With this in mind, we fully agree that more oversight is needed during the plan selection and enrollment process to ensure prospective Medicare beneficiaries are receiving accurate and comprehensive information about their Medicare coverage options. Seniors should be able to trust that information or counseling provided to them about plan options is not perversely linked to financial incentives or bonus structures. The proposed provisions to standardize compensation structures and prohibit commission or volume-based payment incentives that may result in efforts to improperly sway enrollment are an important step forward to protect consumers.

ADDITIONAL COMMENTS ON THE MEDICARE ADVANTAGE PROGRAM

There are several additional areas of comment related to MA that AHA would like to proactively raise for the agency's consideration that are not explicitly raised in the proposed rule. These include:

- Enforcement and compliance of the CY 2024 MA rule.
- The 340B remedy rule and the implications for MA plans and providers.
- The use of artificial intelligence (AI) in the MA program.

We appreciate the opportunity to publicly comment on these supplementary topics given their importance to health care providers and their patients.

Enforcement and Compliance of CMS Rules

Consistent with our <u>October 2023</u> and <u>November 2023</u> letters to CMS, we remain concerned about MA plan compliance with the CY 2024 MA final rules taking effect Jan. 1 and would like to reiterate our recommendations for improving oversight of the MA program. We urge the agency to conduct rigorous monitoring and enforcement of the new rules including plan-level data collection and reporting, regular auditing, pathways for stakeholders to report suspected violations and penalties for non-compliance. Specifically, our recommendations follow.

Data Collection and Reporting. There are limited data reporting mechanisms available to provide CMS with information about plan-level coverage denials, appeals and grievances, or 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. The OIG made a recommendation in 2014 for CMS to identify whether outlier data values reflect inaccurate reporting or atypical performance, and to use reporting requirements data as part of its reviews of MA organizations' performance.⁷ We believe this could be

⁷ https://oig.hhs.gov/oei/reports/oei-03-11-00720.pdf

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a useful approach to conducting data-driven enforcement activity and are encouraged by CMS' discussion in this proposed rule of expanding the reporting requirements for MA plans related to access-indicator metrics discussed above.

In addition, we recommend 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. It appears to us 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 like 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 Required plans, 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. We believe that additional auditing is necessary to ensure compliance with CMS rules, especially those around medical necessity criteria, which are 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, we recommend that CMS regularly audit a sample of MA plan denials, using a similar methodology as the 2022 HHS OIG report, to review MA plan determinations for the appropriate application of Medicare coverage rules and criteria. Without this level of detailed auditing, there will be ample opportunity for certain MA plans to continue circumventing federal rules without detection, rendering the proposed beneficiary protections ineffective.

Pathways to Report Suspected Violations. Patients and health care providers have a high degree of interaction with MA plans as users and providers of health care services and are therefore well-positioned to identify suspected violations of CMS rules that warrant further investigation. In fact, hospitals and health systems often act on behalf of their patients when working with insurers to obtain approval and coverage for medically necessary care, making them especially capable of identifying faulty or outdated program rules or bad actors. Unfortunately, there currently is no streamlined or direct way for providers to report such concerns to CMS. And as described above, when issues are raised, they are frequently labeled as "contractual disputes" and therefore not subject to agency intervention. However, what may appear to be a contractual dispute may be evidence of a violation of federal policy, including systemic issues with the potential for negatively affecting patient care. Without a way for providers to report issues, CMS has no ability to establish a fact pattern needed to engage in enforcement activity. Accordingly, we encourage CMS to establish a process for health care

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providers to submit complaints to CMS for suspected violation of federal rules as part of its enforcement strategy.

Enforcement Penalties. Penalties are a necessary part of enforcement to ensure there is accountability for complying with CMS rules. Given CMS' acknowledgement in the final rule that many of the included provisions are restatements of existing CMS policy, enforcement is critical to ensure meaningful change. We recommend that based on the results of audits and plan-reported data, CMS be prepared to initiate issuing warning letters and Corrective Action Requirements to noncompliant MA plans. If the noncompliance persists, we recommend that CMS impose intermediate sanctions (e.g., suspension of marketing and enrollment activities), civil monetary penalties or terminate the contract. Each of these elements will be critical in 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 and members and consistently act in good faith in trying to follow the rules. To this end, we believe that enforcement actions should be targeted to MA plans who 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.

340B Remedy and Medicare Advantage

Following the Supreme Court's unanimous decision in *American Hospital Association v. Becerra*, HHS issued a final rule in November outlining the agency's remedy for the unlawful payment cuts to certain hospitals that participate in the 340B Drug Pricing Program. The AHA is pleased that 340B hospitals finally will be reimbursed in full for the unlawfully withheld payments through lump sum repayments. **We continue to believe, however, that there is an outstanding policy problem that has yet to be rectified with respect to past underpayments to hospitals by MA plans that mirrored HHS' unlawful payment policy.**

Despite the urging of AHA and other stakeholders, HHS did not address concerns related to MA underpayments in the final rule, noting that these issues are "out of the scope of this final rule." As such, we urge CMS in the context of open CY 2025 MA rulemaking to address the substantial concerns AHA outlined in our <u>August 2023</u> <u>comment letter</u> on the proposed remedy with respect to MA and to make hospitals whole for underpayments from MA plans between 2018 and 2022.

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We also disagree with HHS' assumption that addressing this significant policy problem would constitute an interference with "the payment rates that MAOs [Medicare Advantage Organizations] set in contracts with providers and facilities."⁸ Many MA plans link payment to Traditional Medicare payment rates. Because there is an exact correspondence with those rates in those cases, HHS would not be interfering with MA plan contracts or payment rates. All it would be doing is making clear that its own remedial decision must be followed by MA plans where the MA plans link payment to Traditional Medicare rates.

There is a compelling need for HHS to act. As a direct result of HHS' unlawful payment cuts, providers suffered the exact same fate at the hands of MA plans. With \$10.6 billion in underpayments due to hospitals from Traditional Medicare, and with half of all Medicare beneficiaries enrolled in MA, the harm to hospitals with respect to underpayment from MA plans resulting from HHS' illegal policy would likely be of similar size and scale, amounting to *billions of dollars* of unlawful cuts that have yet to be rectified. The AHA has been made aware by numerous members that MA plans have not repaid hospitals what they are owed in good faith because of the Supreme Court decision and the unlawful payment policy. Accordingly, we urge HHS to take all possible measures within its authority to ensure MA plan compliance with repayment and that, in aggregate, hospitals are made whole for these astronomical underpayments. Indeed, if HHS does not act now, it may well be compelled to act in the future using its prompt payment authorities under 42 U.S.C. 1395w-27(f).

Furthermore, with respect to the recoupment policy that CMS finalized in November, we continue to be concerned that the adverse impact on hospitals under MA will be exacerbated while MA plans will receive a financial windfall because of this policy and at the expense of hospitals and health systems who have been underpaid by billions of dollars. Specifically, under the final rule, HHS will recoup funds from all hospitals by reducing Traditional Medicare payment rates annually by 0.5% for non-drug services. This unlawful and unwise claw back is problematic on its own, but it is especially problematic in the context of this MA windfall. HHS failed to include a corresponding requirement for MA plans to pass the resulting savings from the recoupment (which would accrue to MA plans who apply the 0.5% reduction in payment) to hospitals whose payments were already cut by MA plans between 2018-2022 in connection with the agency's unlawful policy. Since many MA plans pay hospitals according to the

⁸ While CMS notes that it cannot interfere in payment rates that MAOs set in contracts with providers and facilities, it does clarify in the rule and in a separate informational memorandum that was issued on Dec. 20, 2022, that "MAOs must pay non-contract providers or facilities for services and items at least the amount they would have received under Original Medicare payment rules, in accordance with section 1852(a)(2) of the Act (42 U.S.C. 1395w-22)."

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Traditional Medicare payment rates, there is a significant risk that MA plans will pay hospitals a decreased rate going forward because of HHS' recoupment methodology.

This could double the adverse impact of the proposed recoupment on hospitals. In this scenario, many hospitals will have:

- Experienced the same payment reduction in MA as they did under Traditional Medicare between 2018-2022.
- Have not been repaid or made whole for their losses under MA between 2018-2022 because of the HHS' unlawful payment policy.
- Will be subject to further reductions going forward to pay for HHS' mistake if MA plans adopt the recoupment reduction going forward consistent with Traditional Medicare payment rates.

Meanwhile, MA plans will receive a windfall from the government's effort to recoup funds, especially if MA plans continue to refuse to pay the difference between the unlawful 340B policy amounts and what hospitals are owed.

It is simply inadequate to address only half the problem caused by HHS' mistake and to ignore the billions of dollars at stake for hospitals and health systems under MA that are a direct consequence of an illegal policy that was unanimously struck down by the Supreme Court. Accordingly, we urge CMS to use all possible measures under its authority to require MA plans to repay amounts owed to hospitals for underpayments between 2018-2022 and to make hospitals whole for the *full* amount of their combined losses under Traditional Medicare and MA because of HHS' illegal payment cuts.

Insurer Use of AI Tools in the MA Program

In the last decade, the use of algorithms has become prevalent in the MA claims review process. While the proposed rule does not specifically address this topic, we would like to make the agency aware of our observations and concerns with respect to the use of AI tools in the MA program and encourage CMS to consider how new technologies may impact access to services and whether additional oversight is needed. We also recommend CMS consider certain 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.

We regularly hear from our members about concerns with AI tools or software that are automatically denying large volumes of claims. While a plan may indicate it uses AI as a guideline, it appears that in some cases these tools are amounting to a de facto standard for coverage determinations, which raises serious concerns about access to care for MA beneficiaries and parity with coverage under Traditional Medicare where such tools are not used. For example, we are concerned about certain applications of AI Administrator Brooks-LaSure January 5, 2024 Page 13 of 14

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, and then the prediction is used definitively to terminate coverage of services on that date. This appears to happen irrespective of any individual patient's circumstances or the recommendation of the treating medical team. We urge CMS to investigate such applications of AI tools and whether MA enrollees are inappropriately being denied access to covered services that meet Medicare criteria using automated tools; more transparency and oversight is needed to ensure appropriate use.

We recognize that using traditional algorithms or, more recently, discriminative AI models can increase speed and accuracy and reduce fraud and the overall cost of processing claims. However, as noted above, relying on algorithms for claims and appeal processing, especially when automated using predefined criteria, carries significant risks including:

- Violating the legal and contractual obligations of MA plans to provide coverage for medically necessary services that are covered by Medicare.
- Undermining the quality of care and health outcomes of MA beneficiaries by delaying or denying access to needed services, especially for those with complex or chronic conditions.
- Increasing the administrative burden and costs for MA beneficiaries and their providers who must appeal erroneous or unfair denials of claims or early termination of medically necessary services.
- Eroding the trust and satisfaction of MA beneficiaries and providers with the MA program and the insurers that offer MA plans.

To mitigate both the risks associated with current algorithms and AI models used throughout the claims process, as well as to alleviate concerns about how generative AI tools or AI augmented practices could restrict or deny access to care in MA plans in the future as the technology continues to evolve, CMS should carefully consider implementing the following safeguards:

- Establishing clear and transparent standards and guidelines for the development, validation, implementation and evaluation of auto-denial software by MA plans, in consultation with relevant stakeholders such as beneficiaries, providers, regulators and other experts.
- Requiring MA plans to disclose the use and performance of auto-denial software to beneficiaries, providers, regulators and the public, including the criteria, data, algorithms and outcomes of the software.
- Ensuring that the individual circumstances of the patient and the recommendations of their medical team are considered in making coverage determinations and that these important factors are not overridden by automatic or algorithm-assisted denial software.

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- Strengthening oversight and enforcement of existing rules to ensure MA plan compliance with the legal and contractual requirements for coverage and appeals, as well as the quality and performance standards for MA plans; and ensuring plan compliance with these requirements is not eroded by using new tools like auto-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 judgement.
- Banning compensation incentives for clinician reviewers that are based on the volume of denials they approve or uphold.

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 Michelle Kielty Millerick, AHA's senior associate director for health insurance and coverage policy, at <u>mmillerick@aha.org</u>.

Sincerely,

/s/

Ashley Thompson Senior Vice President Public Policy Analysis and Development