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May 29, 2024

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

# Re: CMS 4207-NC, Medicare Program; Request for Information on Medicare Advantage Data

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 provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) Request for Information (RFI) regarding Medicare Advantage (MA) data.

The AHA appreciates CMS' interest in improving MA data capabilities and increasing transparency and oversight of the program as it continues to grow. We applaud the agency's recent rulemaking designed to improve consumer and beneficiary protections for MA enrollees and believe efforts to increase data collection, reporting and transparency in the program will further advance these important aims. Indeed, as enrollment in the MA program has for the first time reached more than half of all people enrolled in Medicare, it is more important than ever to establish and implement stronger data-driven oversight capabilities. Timely and accurate information on MA plan performance and compliance with existing CMS regulations is critical to ensuring that those enrolled in MA plans are not unfairly subjected to more restrictive rules and requirements than Traditional Medicare, which are contrary to the intent of the MA program and run afoul of federal rules.

The AHA has written extensively to CMS and other federal agencies in recent years, including in our response to CMS' <u>August 2022 RFI</u>, articulating serious concerns about the negative effects of certain Medicare Advantage Organization (MAO) practices and policies. These include abuse of utilization management programs, inappropriate denial



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of medically necessary services that would be covered by Traditional Medicare, use of overly restrictive proprietary medical necessity criteria that are not transparent to patients or providers, requirements for unreasonable levels of documentation to demonstrate clinical appropriateness, inadequate provider networks to ensure patient access and unilateral restrictions in health plan coverage applied in the middle of a plan year, 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 health care worker burnout.<sup>1</sup>

Since the August 2022 RFI, CMS has taken important steps to advance and finalize critical rulemaking to address some of these issues, increasing oversight of MA plans and seeking to better align coverage offered by MA plans with Traditional Medicare. We applaud the important beneficiary protections included in the CY 2024 MA final rule, which went into effect in January, and subsequent frequently asked questions (FAQ) guidance issued in February 2024; however, it is clear that more robust enforcement and transparency is needed to ensure compliance with these important coverage protections. Hospitals and health systems across the country continue to report noncompliance with the new rules, including failure to adhere to the two-midnight benchmark, application of more restrictive criteria than Traditional Medicare and medical necessity denials for services that received prior authorization, among others. More troubling, health care providers have limited mechanisms to seek resolution of these violations and are routinely referred back to the plan to address them through contractual dispute resolution mechanisms — even when the issue at hand is a violation of federal law or regulation.

In response, the AHA continues to urge CMS to increase enforcement of existing MA regulations to protect Medicare beneficiaries from inappropriate delays and denials of Medicare-covered services. We believe data collection and reporting on plan performance metrics that are meaningful indicators of patient access are a critical component of an effective enforcement strategy and strongly support CMS efforts to require MA plans to submit additional information necessary to conduct appropriate oversight. This should include public and transparent reporting on plan-level coverage denials, appeals and grievances — along with decision rationales — as well as information on delays in care resulting from plan administrative processes.

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<sup>&</sup>lt;sup>1</sup> Addressing Health Worker Burnout: The U.S. Surgeon General's Advisory on Building a Thriving Health Workforce. 2022. https://www.hhs.gov/sites/default/files/health-worker-wellbeing-advisory.pdf

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Along these lines, we appreciate provisions included in CMS' recent final CY 2025 rule, which lay the groundwork for requiring such important information to be collected to improve program oversight and transparency, including service-level data for all initial coverage decisions and plan level appeals; decision rationales for items, services or diagnoses; and greater transparency on MA plan utilization management and prior authorization procedures. We strongly support data collection in the aforementioned areas CMS has identified and look forward to engaging with the agency on related future rulemaking. Proactive, rigorous and data-driven enforcement is imperative to address persistent problems plaguing the MA program and impeding patient access to care.

In evaluating potential or new data collection and reporting requirements for the MA program, we recommend CMS consider the following:

- Administrative Simplification: New data collection and reporting requirements should be designed to minimize the administrative burden on the health care delivery system and stakeholders.
- Data Utility: CMS should propose a specific plan for how any data it plans to collect will be used, including how certain measures are intended to drive additional program oversight or improvements.
- Public Transparency: Data collection and reporting on the MA program should be made publicly available to increase transparency of the MA program for patients, providers, beneficiary advocates and other stakeholders, and should lend appropriate consideration to preventing disclosure of proprietary information where possible.

Additionally, we urge CMS to consider the unique ways that integrated delivery systems collect and maintain data. The data collected and maintained by integrated delivery systems and other integrated payer-provider organizations may be structured differently from traditional health insurance carriers and thus may require additional information to ensure correct interpretation. For example, integrated health systems may structure prior authorization processes differently from traditional insurers or may have more complete clinical data from providers due to having access to the electronic medical record, which may present nuances in how data from integrated health systems are reported or the extent to which they can be compared to other plans. Any new reporting requirements should accommodate such structural differences for integrated health plans.

Our specific concerns and recommendations around enforcement of CMS rules, gaps in compliance, and data or policy changes needed to conduct appropriate oversight are enumerated in the following sections. In addition, we provide further commentary and recommendations on other aspects of the MA program where additional data or analysis may be needed, such as oversight of prior authorization, access to post-acute care services, vertical integration of insurers, artificial intelligence, timeliness of insurer

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payment for covered services, and appeals procedures. We also raise special considerations for rural and critical access hospitals that are uniquely affected by the growing MA penetration in rural areas. Finally, we discuss implications for the continued rapid growth in the MA program and how it may affect Traditional Medicare, as well as considerations for the future structure and sustainability of the Medicare program.

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 director for health insurance and coverage policy, at mmillerick@aha.org.

Sincerely,

/s/

Ashley B. Thompson Senior Vice President Public Policy Analysis and Development

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# **ENFORCEMENT OF AND COMPLIANCE WITH MA PROGRAM RULES**

Consistent with our October 2023 and November 2023 letters to CMS, we remain concerned about MA plan compliance with the CY 2024 MA final rules and reiterate our recommendations for improving oversight of the MA program. As detailed in the recommendations that follow, we urge CMS to conduct rigorous monitoring and enforcement of the new rules, including plan-level data collection and reporting, regular auditing of compliance, development of formal pathways for stakeholders to report suspected violations and penalties for non-compliance.

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. The Department of Health and Human Services Office of Inspector General (HHS-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.<sup>2</sup> 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 accessindicator 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 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 Required plans, 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. We believe that additional auditing is necessary to ensure compliance with CMS rules, especially those around

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<sup>&</sup>lt;sup>2</sup> https://oig.hhs.gov/oei/reports/oei-03-11-00720.pdf

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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, 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, certain MA plans are likely 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 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 uniquely qualified to identify faulty or outdated plan policies or bad actors.

There is currently no formal, streamlined pathway for providers to report suspected violations of federal rules to CMS. Providers must raise concerns or complaints to the MA plan directly via internal plan complaint procedures or in accordance with other dispute resolution mechanisms identified in the contract. When issues are raised to CMS, they are frequently labeled as "contractual disputes" that are not subject to agency intervention. Some hospitals reach out directly to CMS regional offices with complaints regarding suspected violations of federal regulations but are frequently referred back to the plan in a circular loop that lacks any effective MA plan accountability or regulatory enforcement — even if the issue at hand is broader than an individual contract or dispute. In fact, issues commonly treated as contractual disputes may actually be federal policy violations, including systemic issues with the potential to negatively affect patient care.

Additionally, private dispute resolution mechanisms are not the appropriate mechanism to resolve violations of federal rules. Using contractual mechanisms as the preferred pathway for such adjudication not only absolves MA plans from complying with federal laws and regulations, but also ensures that complaints and resolutions are kept private, circumventing public transparency and agency oversight. In addition, contract dispute pathways require substantial financial resources from hospitals and health systems to seek relief through arbitration or litigation. This not only adds cost and burden to the health care system, but also unfairly burdens small and rural providers that may not have the resources to challenge inappropriate denials through these mechanisms and are therefore forced to absorb the cost of denials if they cannot fund a dispute. Denials that remain unchallenged for these reasons, as well as denials that are overturned through costly contractual dispute resolution mechanisms, all occur outside of CMS' line of sight and impede federal oversight of the program.

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A streamlined pathway for providers to report such issues and to provide some level of accountability and transparency in addressing violations of federal rules is desperately needed. This may specifically include a formal pathway to submit procedural violations or complaints into CMS' Complaints Tracking Module (CTM), as opposed to the current process of sending individual complaints into CMS regional offices, where providers experience a high degree of variability in terms of the response and resolution. Without a formal pathway and appropriate tracking mechanisms, CMS has limited ability to establish a fact pattern needed to engage in enforcement activity or even to be aware of pervasive compliance problems that the agency is charged with addressing. Accordingly, we encourage CMS to establish a process for health care providers to submit complaints to CMS for suspected violation of federal rules as part of its enforcement strategy. In addition, we encourage the agency to publish a redacted database of CTM complaints and their resolutions to increase public transparency into common MA complaints and how they are being addressed.

Enforcement Penalties. Penalties are a necessary part of enforcement to incentivize compliance with CMS rules. CMS' acknowledgement 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 urge 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, 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 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/members and consistently act in good faith 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.

# AREAS OF OPPORTUNITY FOR ADDITIONAL SCRUTINY

While the recommendations above regarding enforcement broadly address the need to increase oversight and enforcement of the CY 2024 MA final rule generally, there are

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specific provisions and issues which we believe warrant greater scrutiny either 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.

**Two-Midnight Benchmark.** In the CY 2024 final rule, CMS codifies 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, requiring that MA plans adhere to the same inpatient admission criteria as Traditional Medicare, which establishes 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 which extend over two midnights are appropriate for inpatient care.

While we anecdotally hear from our members that they have had more frequent success in overturning inappropriate inpatient denials since the new rules took effect Jan. 1 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.

While we continue to work to quantify these trends more broadly to inform the need for greater oversight, there have been disruptions to certain claims-related tracking and reporting mechanisms resulting from the Change Healthcare cyberattack in February 2024 that have impacted the hospital field's ability to report data on relevant metrics. That said, reviewing initial trends using data from Strata Decision Technology, we observe that the percentage of observation stays lasting two or more days for MA patients fell from 24.5% in January 2023 to 16.4% in January 2024, indicating that, at least initially, the regulations are having a substantial impact. Unfortunately, 16.4% is still more than double the rate of observations of two or more days in Traditional Medicare, highlighting that there is still a substantial way to go to achieve parity across all Medicare beneficiaries.

In addition, we continue to receive reports from members about 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. One such denial shared by an AHA member concludes, "although this member was in the hospital two midnights, the member did not meet acute inpatient criteria and/or did not fail observation level of treatment. CMS rules state that reimbursement for acute inpatient level of care is due

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only when the provider facility is rendering acute inpatient level of care treatment." This patient was in the hospital receiving inpatient level of care for eight days. The denial letter goes on to justify the determination by citing that the Medicare Benefit Policy Manual allows the plan to deny this care because "admissions of particular patients are not covered or noncovered solely on the basis of length of time the patient actually spends in the hospital." Although this is a direct quotation from the CMS manual, this text in and of itself should not be used as a rationale to deny care simply because CMS gives plans the authority to do so without addressing the individual merits of the patient's case and condition. While there may be factors other than actual length of stay that can be considered when making a level of care determination, we do not believe CMS intended to create a loophole allowing plans to deny inpatient level payment for a patient who required an 8-day hospital stay. This continues to be an area where there are wide gaps in parity and alignment between coverage of inpatient care under MA and Traditional Medicare.

#### Recommendations

- 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 judgement 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.

Use of Internal Coverage Criteria. The AHA strongly supports recent CMS rulemaking that seeks to create parity between MA and Traditional Medicare in processes and criteria used to make medical necessity determinations. MA plans' use of proprietary medical necessity criteria that are more restrictive than Traditional Medicare and not transparent to patients or providers are pervasive problems in the MA program, frequently resulting in inappropriate denials and reduced access to Medicare-covered services.

In the final rule, CMS established 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). Despite this rule and subsequent reinforcement in the February 2024 FAQs, our members continue to report coverage denials of basic benefits justified with proprietary criteria such as Interqual or MCG. In one instance, a large national plan denied an inpatient admission for a patient with COVID-19 who satisfied the two-midnight criteria and whose care spanned beyond two

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midnights. The plan indicated that inpatient coverage was denied because the patient did not satisfy the MA plan's criteria for inpatient acute level of care, suggesting that the plan is applying additional medical necessity criteria (beyond the admitting clinician's expectation that the patient would require inpatient level care extending beyond two midnights). But it is unclear what criteria was used to make that determination or how it was applied to this specific patient's case.

Such denials are still commonplace where an MA plan indicates that a particular patient case did not meet inpatient level of care criteria, often citing Interqual or MCG, or even making no reference to what criteria was used at all to make this determination. This was precisely the circumstance we understand CMS intended to prohibit in the CY 2024 MA final rule by requiring that MA plans make medical necessity determinations in accordance with Traditional Medicare coverage requirements and restricting the circumstances where plans can use additional coverage criteria to a narrow set of limited instances.

In the final rule and subsequent FAQ, CMS indicates that MA plans may only utilize their own internal criteria when Medicare coverage criteria are not fully established under Traditional Medicare. In these 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)." The regulation establishes that coverage criteria is considered "not fully developed" when "additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently." While CMS notes that it "believes permitting the use of publicly accessible internal coverage criteria in *limited circumstances* (emphasis added) is necessary to promote transparency and evidence-based clinical decisions by MA plans that are consistent with Traditional Medicare," our members indicate that plans continue to widely and indiscriminately use internal coverage criteria as a blanket policy. Accordingly, greater oversight and transparency is needed to prohibit over-extension of the limited flexibility CMS provided plans to apply internal coverage criteria in certain specific circumstances.

We would be pleased to provide the agency with specific examples of denial letters which continue to cite proprietary criteria as the rationale for a denial without any further information about why additional criteria was needed, where the criteria can be found and/or how it was applied to this specific patient's circumstances. Despite CMS' clear guidance and directives to MA plans, in many ways the status guo remains.

Moreover, we are concerned by the lack of transparency regarding how MA plans determine whether Medicare criteria is fully established, which dictates the limited set of circumstances where they can apply internal coverage criteria. It seems that MA plans have been allowed to unilaterally determine when Medicare criteria is fully established, with their decision-making process and conclusions entirely shielded from public view.

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Denial letters consistently continue to reference internal coverage criteria as the rationale for the decision, but do not provide any insight into the analysis conducted to determine that Medicare criteria was not fully established and therefore additional criteria are permissible. Allowing plans to make such vast interpretations of when Medicare coverage policy is or is not fully developed in secret and without transparency into what information is considered in the process gives MA plans carte blanche to continue using internal coverage criteria that are more restrictive than Traditional Medicare. We urge CMS to adopt more rigorous oversight of the circumstances in which plans are applying internal coverage criteria and require transparency around when, why, and how often this is occurring.

#### Recommendations

- Require MA plans to include a 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 was needed to supplement general provisions in making a
  medical necessity determination, as well as information supporting the plan's
  analysis that the Medicare criteria for this service or item is not fully
  established.
- Require MA plans to report data to CMS on the number and percent 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.
- Publish additional guidance on CMS' interpretation of the limited set of circumstances where criteria under Traditional Medicare are not fully established.

Standards for Public Accessibility, High-Quality Evidence and Clinical Benefit. In the limited cases in which internal coverage criteria can be utilized, § 422.101(b)(6) requires such criteria to be publicly accessible and based on widely used treatment guidelines or clinical literature. Hospitals and health systems across the country continue to report that plans are relying on third-party additional coverage criteria, such as Interqual or MCG, without providing sufficient access to the clinical foundation and criteria used to make this determination or making that information publicly available. While some insurers have made internal coverage criteria publicly accessible in accordance with CMS requirements, many have not, and continue to perpetuate barriers for patients and providers to access this information. For example, an AHA member reports that they have asked a particular MA plan repeatedly to point them to where their medical policies, which establish specific definitions of medical diagnoses and other coverage criteria, are available online as required. The plan has consistently reported that they are not online, have no plans to make such documents available online, and the only way to get them is to ask the provider's account representative.

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In addition, we routinely still see denial letters that say "the member did not meet acute inpatient criteria" but no explanation is provided for what the criteria is or how the patient's condition relates to the specific criteria and clinical scenario. In other cases, seemingly random pieces of evidence are cited to justify the denial without any apparent connection to the individual case or patient's circumstances. For example, one AHA member, who requested inpatient admission for an MA patient with complications related to Chronic Obstructive Pulmonary Disease, was told that inpatient care is only permissible when consistent with Interqual guidelines. Interqual cites separate guidelines from the Global Initiative for Chronic Obstructive Lung Disease as the foundation for making level of care decisions for patients with COPD. However, the resource cited does not address or provide any information or guidance on level of care or the appropriateness of inpatient versus outpatient care for treating COPD. In our view, a citation to such a resource does not meet CMS' evidentiary standard, and we are concerned by the frequency with which plans rationalize a level of care determination by citing evidence that actually has no bearing or significance in relation to the clinical appropriateness of inpatient versus outpatient care.

Furthermore, hospitals and health systems have reported complete and widespread noncompliance with the new CMS requirement for plans to demonstrate that any internal criteria used provide clinical benefit to the patient that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services. We have yet to see any such analysis produced by a plan or shared with us by a member organization reflecting that MA plans are demonstrating the appropriateness of additional criteria and the requirement that they provide clinical benefit to the patient. Denial letters continue to cite Interqual, MCG or other proprietary criteria with no information or discussion about clinical benefit. This is disappointing, given the strength and clarity of CMS' February 2024 FAQ, which provided a distinct directive to plans regarding the standards set forth in § 422.101(b)(6)(i)(A) and the burden of proof required to demonstrate compliance. With this in mind, we believe stronger auditing and scrutiny with appropriate enforcement action is needed to ensure compliance.

#### Recommendations

- Require MA plans to demonstrate how the requirements of 422.101(b)(6) are met for each specific clinical condition for which the MA plan adopts an internal coverage criterion. Clinical benefit must be clearly demonstrable from the clinical literature meeting the evidentiary standard, for that specific clinical condition and/or patient population.
- Audit MA plan denial letters to determine if the information provided to
  patients and providers about coverage of requested items or services reflects
  evidence of compliance with § 422.101(b)(6) including with respect to the use
  of internal coverage criteria, public accessibility, high-quality evidence and
  clinical benefit to the patient.

- Require MA plan Utilization Management Committees to annually attest to CMS that their internal medical necessity criteria and application procedures meet CMS requirements.
- Conduct targeted audits to ensure that plan utilization of internal coverage criteria is properly aligned with CMS rules and regulations. Such audits should include a review of large third-party medical necessity compendiums to ensure that plan guidelines are sufficiently based on acceptable evidence that meets CMS' evidentiary standard.
- Require MA plans to proactively provide information to patients and providers (including on denial letters) on how to access internal coverage criteria used in medical necessity determinations that CMS requires to be publicly accessible.
- Clarify that a policy requiring contracted providers to contact their plan account representative to access internal coverage criteria does not meet the standard of public accessibility.

Retrospective Medical Necessity Denials for Services with Authorization. AHA strongly supports language codified in the 2024 final rule that prohibits an MA plan from retroactively denying a service as medically unnecessary if that service had previously received prior authorization. Specifically, CMS states, "if the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter) or if there is reliable evidence of fraud." While this provision codified existing and longstanding policy in the Medicare Managed Care Manual, Chapter 4, Section 10.16, we believe including this requirement more explicitly in federal regulation was an important and much-needed update given challenges with MA plan adherence.

Unfortunately, we continue to receive widespread reports and examples of patient cases that received authorization at the time of the service or admission, only to be retroactively denied, sometimes months later, often by a third-party vendor hired by the MA plan. We have predominately received examples of plan noncompliance with this provision related to inpatient hospital admissions.

In some cases, MA plans will attempt to cite an alternate reason besides medical necessity for the retroactive denial to circumvent this provision, citing an unrelated readmissions policy or site of service policy that is more restrictive than traditional Medicare or summarily concluding the denial is not, in fact, a medical necessity or coverage determination. One plan recently justified a retroactive medical necessity denial to a member hospital citing that "inpatient determinations are level of care decisions and not approvals or denials of coverage." Similarly, plans continue to characterize these decisions as payment decisions, not medical necessity or coverage determinations. Such denials reinforce our concerns that certain national plans may be

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willfully misinterpreting recent CMS guidance by reviewing cases that were authorized for inpatient status and later having a third-party vendor unilaterally downgrade the stay to observation status, claiming that such a downgrade is not a coverage determination and therefore rules prohibiting subsequent denial of an authorized service don't apply. In this case, the plan representative went on to cite that their utilization review team makes initial level of care decisions for MA members' hospital stays based on MCG guidelines, which is a further violation of CMS requirements. It does not appear that MCG guidelines are merely being used as criteria to demonstrate the provider's professional judgment was unreasonable, as CMS emphasized in its February 6, 2024 memo to MA plans, but rather as an additional set of criteria on top of Medicare rules. This plan communication is dated March 2024; we would be happy to share it with CMS upon request.

We recognize and appreciate that CMS expressly addressed several of these cases in the February 2024 FAQ guidance on certain post-claim review audits. In that FAQ, CMS directly addressed MA plan audits that retroactively deny authorized care, including those that categorize such denials as "payment reviews" that are not "organization determinations" or "level of care or medical necessity reviews." In response, CMS helpfully stated, "we disagree with those characterizations of decisions that are denials of coverage or otherwise a refusal to provide or pay for services, in whole or in part, including the type or level of services ... We reiterate here that the refusal to provide or pay for services, in whole or in part, including the type or level of services (e.g., inpatient services versus outpatient services) is an organization determination by the MA plan under § 422.566(b)(3)." Such a determination is subject to appeal rights and must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine appropriate for the services at issue. Statements from the MA plan noted above citing that level of care decisions are not coverage decisions directly contradicts this CMS policy.

While we believe the CMS FAQ language is very clear and serves as a binding directive to plans that refusing to pay for inpatient level of care is an organizational determination subject to full appeal rights, we are troubled that certain large commercial plan behaviors, including those that CMS indicates are impermissible in the FAQ guidance, persist. Accordingly, we urge CMS to increase auditing and enforcement of these provisions related to retroactive denials of authorized care, as well as plan efforts to mis-categorize level of care decisions as anything other than an organizational determination subject to full appeal rights for the purpose of circumventing CMS regulations.

Finally, we would like to draw CMS' attention to another practice we have observed in recent reports from our members that appears to increase complexity for adjudicating inpatient admissions and enforcing CMS rules that prohibit retroactive denials of authorized services. MA plans may require hospitals to provide advance notification of an inpatient admission for covered members. Historically, advance notification has

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required the hospital to submit basic information about the facility and location, admission date and type, ICD diagnosis code(s), and admitting physician. However, plans are increasingly using advance notification as the first step in determining member coverage based on medical necessity, and are, in some cases, using this process to make coverage determinations for level of care. They may also subsequently require a prior authorization on top of the advance notification. This duplicates a medical necessity review for any services that also require prior authorization, giving MA plans multiple opportunities to review and deny coverage. It also appears to circumvent the CMS regulation prohibiting post-claim denial of preauthorized services for medical necessity reasons, as the plan uses the advance notification process to make a medical necessity determination instead of prior authorization.

In one such case, a hospital submitted an advance notification to a large, national insurer for an inpatient admission. The insurer issued no response, either favorable or unfavorable to inpatient status. After discharge, a third-party vendor audited the level of care and downgraded the claim to observation status. The hospital inquired, as the plan conducted a level of care determination at the advance notice stage and did not provide a notice of denial or downgrade. In response, the plan reported that they do not send approvals for authorizing inpatient level of care at the advance notification stage but would only let the hospital know if their utilization management team determined the case was instead more appropriate for outpatient status. This means the plan is conducting a full medical necessity review to determine level of care at the advance notification stage yet tries to preserve their ability to deny the service in a post-claim review for medical necessity because the plan did not classify the review as a prior authorization. It also furthers the concerning practice of treating level of care determinations as something other than a coverage or payment determination, which should be subject to full appeal rights and review as an organizational determination. Any plan policy that requires advance approval or notification for a service involving a medical necessity determination should be considered a prior authorization, regardless of the terminology a plan might opt to use.

#### Recommendations

- Reiterate in guidance that coverage of a service requires payment of the service.
- Draw a clear distinction in guidance between an organization determination (whether a service is covered) and the pricing or payment for that service (a payment dispute regarding methodology or calculation).
- Conduct rigorous auditing of retroactive denials of services that have received prior authorization.
- Collect data on MA plan level of care determinations that downgrade care from inpatient to observation status, including the rationale.
- Audit plan processes for conducting level of care reviews to ensure that any refusal to provide or pay for services, in whole or in part, including

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- downgrades of inpatient care to observation status, is an organization determination by the plan subject to requirements under § 422.566(b)(3).
- Penalize plans, where appropriate, for applying policies or practices that directly violate or intend to circumvent CMS rulemaking, including terminology changes that mis-categorize denials or downgrades as something other than a coverage determination.

Relevant Medical Expertise of Clinical Reviewers. AHA strongly supports the changes that CMS finalized to § 422.566(d), which seek to ensure that MA plan clinicians reviewing organizational determinations of medical necessity must have appropriate training in the field of medicine for the service being requested. Specifically, the final rule requires that the organizational determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria.

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 judgement 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 judgement of a treating physician who specializes in rehabilitative care.

While the policies codified in the final rule 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. How can the requirements to ensure the appropriate medical training of clinician reviewers be validated if patients and providers are unable to even identify the person who reviewed the denial? Accordingly, we urge CMS to 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.

#### Recommendations

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- Require MA plan clinicians who review adverse organizational determinations to sign denial letters with their signature, full printed name, NPI number, and credentials, including board certifications and areas of specialty expertise or training.
- Require MA plan clinicians who review adverse organizational determinations
  to individually certify or attest that they have appropriate training in the field of
  medicine for the item or service being requested that is sufficient to make a
  sound medical necessity determination.
- Conduct routine audits of the credentials of MA plan clinicians reviewing and signing organizational determinations to validate compliance with CMS regulations.
- Require that the provisions of § 422.566(d) specifying the appropriate expertise of medical reviewers for organizational determinations also apply to peer-to-peer consultations between MA plan reviewers and the treating provider.

Sepsis Denials. Certain MA plans have unilaterally stopped reimbursing providers for the care necessary to treat certain cases of early sepsis occurring in inpatients. Specifically, these plans are choosing to no longer follow the Sepsis 2 guidelines, which have been adopted by most practicing physicians and serve as the CMS standard for sepsis coverage. Instead, these plans have unilaterally applied a different standard (Sepsis 3) for purposes of determining provider reimbursement only. This standard more specifically focuses on later stages of sepsis and has been validated only in early retrospective studies and only as an outcome/mortality predictor. It is not supported by current clinical best practices, nor is it recognized by current coding or payment methodologies used by CMS. CMS representatives have even acknowledged that "as opposed to early identification, the [Sepsis 3] definitions may delay the diagnosis of sepsis until patients are much sicker." In short, plans' adoption of Sepsis 3 does not change the way providers care for patients with sepsis; it simply enables the plan to decline reimbursement for early sepsis interventions, resulting in inappropriate underpayment to providers who continue to deliver medically necessary care.

One independent hospital noted that these sepsis-related plan policy changes result in a per-case reduction in reimbursement ranging from \$500 to \$6,000, depending upon the factors involved. This represents a loss of more than \$100,000 annually for this single hospital, attributed solely to inappropriate health plan sepsis coding changes.

While the CY 2024 MA final rule does not directly address sepsis coding changes, we continue to believe that CMS policy changes intended to ensure parity in coverage between MA and Traditional Medicare should prevent insurers from applying more

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<sup>&</sup>lt;sup>3</sup> https://jamanetwork.com/journals/jama/fullarticle/2536619

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restrictive coverage or payment rules than Medicare. This includes insurer payment classifications for sepsis care that are expressly designed to reduce payment to providers for Medicare-covered services without regard to the medically necessary care provided to patients to treat sepsis.

Insurers routinely argue that sepsis reimbursement policies are payment issues and therefore they have sole discretion to determine how contracted providers are paid for these services. We reject this notion and believe it directly contradicts CMS' policy in the CY 2024 final rule that "it is irrelevant whether Traditional Medicare considers the criteria part of a coverage rule or a payment rule" ... "because MA organizations provide coverage by furnishing, arranging for, or *making payment for* [emphasis added] Part A and Part B items and services." MA plans that continue to adopt payment or coverage criteria that differs from Traditional Medicare, including for the purpose of paying for sepsis care, are in direct violation of § 422.101(a) and (b). We urge CMS to audit and enforce these provisions of the final rule and to examine MA plan payment policies which are being widely adopted for the purpose of denying or reducing payment for Medicare-covered services.

#### Recommendations

- Require MA plans to use Sepsis 2 criteria for coverage and payment of sepsis care, consistent with CMS policy and applicable clinical guidelines. This would preclude plans from unilaterally applying Sepsis 3 criteria.
- Include coverage and payment of sepsis care in CMS audits related to enforcement of the CY 2024 final rule and § 422.101(a) and (b).
- Require MA plans to report information about sepsis denials and payment criteria to CMS to be made publicly available for the purpose of increasing program integrity and transparency and ensuring parity with Traditional Medicare criteria.

Clinical Validation Audits. An increasingly common tactic that certain MA plans are adopting to lower or deny provider payment is conducting clinical validation audits on large volumes of MA claims. Through these audits, MA plans disregard a reported diagnosis on a claim, characterizing the condition as invalid and modifying the licensed treating provider's medical diagnosis to deny coverage and payment for services that were rendered to treat that condition. This occurs even while MA plans universally recognize that the diagnoses in question are supported by physician documentation within the medical record. However, they remove the diagnosis from the claim based on their use of different clinical criteria used to establish a definitive diagnosis, making the case that the treating provider incorrectly diagnosed the patient. This type of analysis is conducted after the fact by a clinician at the health plan (or increasingly by a non-clinician under supervision of a clinician), who reviews the medical record but who has never even seen, examined or treated the patient.

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Clinical validation audits are beyond the scope of the widely accepted practice of conducting DRG (coding) validation audits, which is a distinct process during which physician documentation is reviewed to determine whether the correct codes and sequencing were applied to the billing of the claim based on Official Guidelines for Coding and Reporting. DRG validation audits are conducted by a certified coder who is evaluating the accuracy of the claim coding based on what was documented by the physician— not re-evaluating the physician's assessment of the patient's medical condition and diagnosis. Clinical validation audits, in contrast, are a separate process, which involves a clinical review of the medical record documentation by a plan clinician to see whether the patient truly possesses the conditions that were documented. The MA plan clinical validation audit results in unilateral decisions to remove a diagnosis from a claim based on differing clinical criteria than what was used by the treating physician to establish the diagnosis. Consequently, this downgrades the MS-DRG to a lower-weighted MS-DRG that does not accurately reflect the patient's severity of illness, complexity of the case, or the services performed. There are varying criteria used to establish diagnoses in addition to the overall clinical picture of the patient. However, it is important to note that there is not one nationally recognized or accepted set of criteria used by all physicians or clinicians legally accountable to establish diagnoses.

The justification for second-guessing the judgement of the physician who diagnosed and treated the patient is extremely problematic. For example, in one case, an MA plan surmised during a retrospective clinical validation audit that the patient's heart attack diagnosis was "not clinically significant." This patient was transferred from a small community hospital with troponin (a protein that is released into the blood during a heart attack) more than 17 times the normal limit. Four separate board-certified cardiologists saw the patient during her stay, all agreeing the correct diagnosis was non-ST-Elevation Myocardial Infarction (NSTEMI), which is a type of heart attack. The patient received medically necessary treatment for a heart attack including serial cardiac labs. EKG. coronary angiography, echocardiogram and cardiac catheterization. Despite the concurrence of four separate cardiologists, the health plan reviewer — who is not a cardiologist, or even a physician — determined the heart attack was not clinically significant because the troponin was "slightly" elevated. The diagnosis of heart attack was unilaterally removed from the claim and disregarded, resulting in payment that does not reflect the cost of resources delivered to the patient in evaluating, diagnosing and treating the heart attack. This should be viewed as an adverse medical necessity determination where coverage and payment for services rendered are being unilaterally denied by the plan.

CMS' statement of work for recovery audit contractors (RACs) prohibits them from performing clinical validation audits in the Traditional Medicare program, but such audits have become pervasive among MA plans, creating further disparities in coverage and

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payment of services in the MA program.<sup>4</sup> In other words, clinical validation audits have become a convenient way for certain MA plans to ignore a physician's documented diagnosis and decline to pay the hospital for the resources required to diagnose and treat a legitimate medical condition — shirking their obligation to pay for millions of dollars of Medicare-covered services that were delivered to beneficiaries. The payment reductions stemming from such audits have serious financial consequences for hospitals and health systems.

One mid-sized independent hospital reported a loss of **\$2 million last year alone** attributed solely to clinical validation audit payment reductions, up from several hundred thousand dollars in 2020. This reflects dramatic growth in what appears to be an increasingly lucrative MA plan tactic to lower provider payment without regard to the services that were delivered to a Medicare beneficiary.

A large health system that operates approximately 50 hospitals tracked clinical validation audits between 2018 and 2023 and identified that the combined financial impact of claims that were either reduced or received no payment at all as a result of this specific type of audit amounted to **more than \$32 million in lost revenue** for the health system, of which **\$13.5 million** in lost revenue was for care provided to MA patients. The volume of clinical validation audits has grown steadily since first occurring in 2018, and in 2023, this health system experienced payment reductions of \$16 million from a single insurer attributed solely to clinical validation audits. Among the MA cases, the average per case reduction was approximately \$4500, while another independent hospital reported their average payment reduction from clinical validation audits was \$6500. In addition, the average age of claims that were subjected to inappropriate clinical validation audit denials for the large health system was **over two years old** by the time a final determination was reached.

Notably, clinical validation audits resulting in low or no payment are more prevalent among MA plans compared to other insurance types, suggesting that these audits specifically target MA claims and could be financially motivated. For example, the aforementioned health system provided data reflecting that between 2018-2023, MA plans were more than twice as likely to zero-pay a hospital claim as a result of findings from a clinical validation audit than a managed Medicaid organization — and more than three times as likely to do so compared to a commercial insurer. Reduced payments, which are more common than zero-payments, followed similar trends. MA plans were

<sup>&</sup>lt;sup>4</sup> https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/090111RACFinSOW.pdf

<sup>&</sup>lt;sup>5</sup> Clinical validation audits first started for this provider in 2018 but have dramatically increased in volume each subsequent year, so while the figures represent data collected between 2018-2023, the payment reductions reported are concentrated in more recent years and reflect a growing concern. The financial impact in 2023 may be understated, as clinical validation audits are often conducted post-payment and claims in the second half of 2023 may still be undergoing appeals or subject to further audits.

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37% more likely to reduce payment because of a clinical validation audit than a commercial insurer, and nearly five times more likely to do so than a managed Medicaid organization.

#### Recommendations

- Prohibit clinical validation audits in the MA program consistent with practice
  of the RACs under Traditional Medicare. Specifically, we urge CMS to require
  audits conducted by MA plans to be consistent with the clinical criteria and
  clinical decision-making of the physician of record as supported by medical
  record documentation and that such audits are not more restrictive than or
  inconsistent with Traditional Medicare.
- Clarify that any plan, policy or audit that applies criteria that dictate specific definitions of medical diagnoses is considered additional coverage criteria that must adhere to the requirements set forth in 422.101(b)(6).
- Clarify that a clinical validation review or audit is a medical necessity determination with respect to the diagnoses under review that would be subject to the protections and appeal rights of an adverse organizational determination.
- Require health plan clinicians conducting clinical validation audits to have appropriate medical expertise in the service or condition being reviewed and prohibit clinical validation reviews by individuals whose scope of practice does not include making a medical diagnosis.
- Prohibit MA plans from using any encounter data tied to a hospital admission in which a diagnosis is invalidated as the basis for which it reports the invalidated diagnosis to CMS as a hierarchical condition code (HCC).
- Require MA plans to report to CMS a list of all invalidated diagnoses with encounter data so CMS can validate the MA plan's HCC reporting.
- Require MA plans to identify the new, lower-weighted DRG on remittance advice in cases where a clinical validation audit results in reduced payment.
- Require MA plans to identify the reduction in payment as a denial, not a contractual adjustment or other classification that may circumvent appropriate oversight and identification of the unilateral DRG reduction.
- Prohibit MA plans from recouping alleged overpayments related to a clinical validation audit that are being appealed until appeals have been completed.
- Require MA plans to report information about clinical validation audits to CMS, to be made publicly available, for the purpose of increasing program integrity and transparency. Mandated reporting should include information about clinical validation audits such as the frequency of clinical validation audits in MA compared to other lines of business; the number and percent of claims reduced and paid zero as a result of a clinical validation audit; the average aging on claims subject to clinical validation audits; the total dollar amount of reduced or zero-pay claims resulting from clinical validation audits; the rationales for removing conditions codes from a claim; the qualifications

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of the reviewing clinicians and areas of expertise in relation to the services or diagnoses being reviewed; the criteria being used to determine if a diagnosed condition was present or not; and the growth in such audits over time.

# PRIOR AUTHORIZATION

We commend CMS for finalizing <u>new regulations</u> in January 2024 that will remove barriers to patient care by streamlining the prior authorization process. Hospitals and health systems especially appreciate the inclusion of MA as a regulated plan type under this rule and believe the finalized policies will improve timely access to care for Medicare beneficiaries and enable clinicians to focus more of their time on patient care instead of paperwork. While we are grateful for CMS' strong commitment to burden reduction and streamlining the authorization process, we also believe there is an important opportunity for continuous improvement for processes that have a direct impact on patient access and outcomes. In this spirit, we offer several additional policy recommendations to continue building on the important foundation established by the final prior authorization rule.

Inclusion of Drugs Covered Under the Medical Benefit. As we mentioned in our March 2023 comments on the Advancing Interoperability and Improving Prior Authorization Processes proposed rule, we believe including drugs covered under a patient's medical benefit in the Prior Authorization Application Programming Interface (API) is technically feasible. Therefore, plans implementing the regulation already will have the functionality necessary to apply the requirements to processing authorizations for drugs covered under the medical benefit. Prior authorization for specialty drugs is extremely common and often requires significant provider resources to get approval for medications, which are frequently part of crucial treatments for cancer and other urgent conditions. The protections and efficiencies contained in the final rule are imperative for patients with complex conditions who require multiple types of time-sensitive medications and drug therapies. For MA beneficiaries to fully realize the transparency and process improvements from the Prior Authorization API, we urge CMS to include medical benefit drugs in the electronic prior authorization standard requirements. In the final rule, CMS indicated that it anticipates engaging with the public on this topic in the near future, and we look forward to the opportunity to provide any additional insight that would be helpful to the agency as its plans future rulemaking.

Reduce Turnaround Time for Prior Authorization Requests. In the final rule, CMS established new timeframes for standard and expedited prior authorization requests. While we appreciate and strongly support the codification of a shorter timeframe for responding to prior authorization requests, we urge the agency to consider additional action to further reduce prior authorization timeliness standards. This is especially

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important given the well-documented negative effects of prior authorization when used excessively or inappropriately, which frequently leads to delays in medically necessary care. Shorter turnaround timelines will also be increasingly feasible as the required technology standards evolve and are implemented. The Prior Authorization API required in the final rule could effectively eliminate the current administrative delays caused by slow delivery of medical documents and will allow for clinical information to be delivered in real time, eliminating the need for a week-long turnaround time. As such, we recommend CMS require MA plans to deliver prior authorization responses within 72 hours for standard, non-urgent services and 24 hours for urgent services.

**Enforcement.** In the final rule, CMS declined to address specific potential compliance and enforcement actions. While we appreciate that each CMS program oversees compliance under existing program authorities and responsibilities, we urge CMS to create mechanisms whereby the data reporting requirements in the final rule are closely monitored and used to guide targeted oversight and enforcement activities. MA plan compliance with CMS rules has a direct impact on an increasingly large share of Medicare beneficiaries' access to care and outcomes. Accordingly, we also recommend that CMS regularly audit a sample of MA plan denials and timeframes to identify and hold responsible those plans that are out of compliance with federal rules.

#### Recommendations

- Include medical benefit drugs in the electronic prior authorization standard requirements.
- Further shorten the prior authorization turnaround time standards for plan responses to 72 hours for standard, non-urgent services and 24 hours for urgent services.
- Regularly audit a sample of MA plan prior authorization responses and denials to assess timeliness and compliance with new standards; this is critical to identify and hold responsible those plans that are out of compliance with federal rules.

#### **ACCESS TO POST-ACUTE CARE SERVICES**

AHA commends CMS for the significant steps it has taken in recent rulemaking and guidance to address the serious concerns AHA and other stakeholders have raised regarding MA beneficiary access to medically necessary post-acute care (PAC) services. As CMS knows, institutional PAC providers, including inpatient rehabilitation facilities (IRFs), long-term acute hospitals (LTCHs), skilled nursing facilities (SNFs) and home health agencies (HHAs) play a vital role for recovering Medicare beneficiaries. These providers work to restore function and allow beneficiaries to return to their lives after a serious illness or injury, usually after an acute care hospitalization.

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We strongly support the policies CMS codified in the CY 2024 final rule, which clarify the coverage criteria that may be used for PAC admissions, the appropriate use of prior authorization and continuity of care requirements for patients. We also appreciate the important guidance CMS provided to MA plans in the February 2024 FAQ regarding coverage of PAC services and the requirements to provide coverage consistent with Traditional Medicare. Specifically CMS codifies that "if a patient is being discharged from an acute care hospital to a post-acute care facility that would be covered under Traditional Medicare and the patient's attending physician orders post-acute care in the specific type of facility (i.e., Skilled Nursing Facility (SNF), Long Term Care Hospital (LTCH)) and the patient meets all applicable Medicare coverage criteria for admission into that facility type, the MA organization cannot deny admission to that post-acute setting and/or redirect the care to a different setting." These are critical protections for patients and needed to ensure access to post-acute care service within the MA program.

MA Plan Compliance with CMS Requirements for PAC. While the new rules and guidance take important steps forward to ensure patient access to appropriate PAC services, we continued to be concerned about instances of MA plan noncompliance with these provisions. Prior to the effectuation of the new rules, the Department of Health and Human Services Office of Inspector General highlighted PAC services as one of the top service categories experiencing inappropriate denials for covered services, so it is not surprising that more frequent and targeted auditing is needed specifically to ensure access to PAC.

Unfortunately, inappropriate denials for PAC through prior authorization have continued largely unabated in 2024, despite the new rules and guidance. This is especially true for hospital-level PAC, namely IRF and LTCH care. Members report little or no change in inappropriate denials, including use of proprietary guidelines that contradict CMS coverage rules and use of unqualified medical reviewers or medical reviewers without adequate knowledge of the patient's condition. In addition, MA plans continue to fail to provide rationale for these denials or cite third-party criteria that is inconsistent with Medicare coverage rules.

By way of example, one large provider of IRF services reports they continue to have approximately a quarter of all requests for IRF admissions denied by MA plans, despite these patients being thoroughly screened for compliance with the CMS IRF coverage rules. In addition, a large LTCH provider has had more than 20% of their requests denied in 2024 thus far. As just one example, one of these cases was an 81-year-old beneficiary who was originally admitted to the acute care hospital for a potential heart failure, became dependent on a ventilator, and remained admitted for 38 days while the hospital family sought admission to an LTCH. The MA plan denied LTCH admission on the erroneous basis that the patient would not need an extended stay and that the patient had tolerated some degree of ventilation weaning. After appeals were also

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denied, the patient was discharged to a SNF. Within 24 hours the patient was readmitted to the acute care hospital in acute respiratory failure and shock.

Acute care hospitals and PAC providers continue to face examples like these daily. It is vital that CMS implement more oversight and conduct regular audits of prior authorization determinations for PAC. This should include reviews of the criteria being used by MA plans, the rationale provided for denials, and reviewer qualifications. In addition, MA plans should be required to report in-depth data regarding their PAC admission determinations, as well as the turnaround time for these decisions, which is especially consequential for hospitalized patients.

**Network Adequacy for PAC Providers.** In addition, we wish to reiterate our concerns about challenges with inadequate MA plan provider networks for PAC providers. It is critical for providers that deliver basic benefits covered by Medicare to be appropriately represented in MA plan networks. Current MA network adequacy rules do not include specific requirements that IRFs, LTCHs and HHAs be included in provider networks. This is a problematic omission that can directly impede patient access to covered services.

Inadequate networks of PAC providers present challenges for patients referred for downstream specialized care that is not provided by the referring hospital, such as services covered by Traditional Medicare for IRFs and LTCHs. These settings provide care through interdisciplinary care teams with specialized clinical training and treatment programs critical to achieving patients' rehabilitation and recovery goals. Insurance constructs resulting in inadequate PAC provider networks are a critical barrier to patients accessing these specialized services to which they are entitled. For example, we commonly hear from PAC providers that MAOs will refuse to contract with IRFs in a given market. In one such case, an MAO reported that they do not believe they need IRFs in the network. In others, MAOs have reported that they believe MA enrollees' rehabilitation needs are being met by non-IRF (i.e., SNF) providers in the plan's network. One of these circumstances has resulted in there being *zero* in-network IRFs for most of the counties in a state with high MA penetration.

In another recent case, a member hospital system reported that a patient could not be safely discharged to home without in-home support, but the patient's MAO only contracted with one HHA in that geographic area. Unfortunately, the HHA had a full patient census and was not taking new patients. Efforts to receive MAO authorization for an out-of-network home health provider were not successful, so the patient was forced to stay in the hospital longer than medically necessary until they could be safely discharged to home without support. Patients should not have to be hospitalized for longer than needed due to inadequate MAO networks or other policies that restrict access to appropriate PAC services.

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These examples are commonplace and serve as a clear indication that more rigorous network adequacy standards are needed for PAC providers. Especially now that CMS has explicitly stated that MAOs must cover IRF, LTCH and HHA services when coverage requirements are met, it logically follows that MAOs should be required to include these providers in their networks. Failure to add this requirement undercuts CMS' recent efforts to ensure parity for MAO beneficiaries. Therefore, we recommend that CMS add a requirement that IRFs, LTCHs and HHAs be explicitly added to MA network adequacy requirements and that standards are adopted to ensure there are a sufficient number and type of each PAC facility in MAO networks. The size and bed capacity of such facilities should also be considered in developing stronger network adequacy requirements for PAC facilities, as even in cases where there are a specified number of PAC facilities available in a certain geographic area, there may not be available beds — further restricting patient access.

#### Recommendations

- Conduct more frequent and targeted audits of MA delays and denials for PAC services, including the criteria being applied to evaluate admissions for facility-based PAC services and the rationale for denials.
- Collect and publicly report data on the average turnaround time from when a
  referring hospital requests to transfer a patient until MA plan approval (at the
  plan level) to identify plan performance issues related to timely access to
  PAC services.
- Require that IRFs, LTCHs and HHAs be explicitly added to MA network adequacy requirements and that standards are adopted to ensure there are a sufficient number and type of each PAC facility in MA networks.

#### VERTICAL INTEGRATION OF INSURERS

The AHA is deeply concerned about the astronomical growth and vertical integration of certain national health insurance conglomerates. Consider the following facts:

- UnitedHealth Group took in over \$1 billion a day in revenue in 2023, with nearly 15% year-over-year revenue growth. Its profits alone were \$22 billion. It is the No. 5 company on the Fortune 500 list topped only by household names like Walmart, Amazon, Exxon, and Apple. If it were a country, it would rank 42nd in the world in Gross Domestic Product.
- CVS/Aetna is the No. 6 on the Fortune 500, just behind UnitedHealth Group. Its total revenue in 2023 exceeded \$371 billion. Nearly 26 million people get coverage from CVS/Aetna plans, and the company reported that it filled about 1.69 billion prescriptions in 2023.

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> Elevance took in \$170 billion in revenue last year, with 9% revenue growth yearover-year. It covers over 47 million Americans and serves an additional 105 million people through its subsidiary, Carelon.

These health care Goliaths often leverage their market power to financially enrich themselves at the expense of patients, health care providers, employers and the federal fisc. The size and scope of national insurers has become so enormous — and their potential anticompetitive impact on access, affordability and innovation so profound — that greater scrutiny, transparency and accountability is urgently needed to protect patients and our increasingly fragile health care delivery system.

The MA program is illustrative of the dangers of this massive consolidation. Today, just two large national insurers control nearly 50% of the MA market share.<sup>6</sup> A recent study reflected that the top three large-group insurers in the commercial market hold an average of 82.2% of the market share in each state.<sup>7</sup> Health insurers use this market power to implement policies that compromise patient safety and raise costs for every stakeholder in the system. Whether it's prior authorization delays, denying medically necessary coverage or forcing patients to try potentially ineffective treatments or therapies, these multibillion-dollar companies are causing a range of harms for patients, providers and the government.<sup>8</sup>

A particular problem is the rampant acquisition of physician practices by these national insurers. They have spent billions of dollars in recent years to purchase doctor practices across the country. For example, UnitedHealth Group, under its subsidiary Optum, acquired Crystal Run, Kelsey-Sebold and Atrius Health, among others, in the past three years. In 2023 alone, CVS Health spent over \$18 billion to acquire both Signify Health and Oak Street. Once acquired, there is mounting evidence that these companies are driving up costs for the health care delivery system. Studies have shown that highly concentrated insurer markets are associated with higher premiums. But, critically, insurers likely do *not* pass on to consumers any savings achieved through lower provider rates.<sup>9</sup>

Fortunately, the focus on concerns about insurer consolidation and vertical integration has increased dramatically in recent years, as has scrutiny of insurer acquisitions and business practices. Earlier this year, the U.S. Department of Justice launched an antitrust investigation into the potential anticompetitive effects of UnitedHealth Group's integration, including the relationship with their owned physician network Optum.<sup>10</sup>

<sup>6</sup> https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf

<sup>&</sup>lt;sup>7</sup> https://www.aamcresearchinstitute.org/our-work/data-snapshot/why-market-power-matters

<sup>&</sup>lt;sup>8</sup> <a href="https://www.aha.org/white-papers/2022-07-28-commercial-health-plans-policies-compromise-patient-safety-and-raise-costs">https://www.aha.org/white-papers/2022-07-28-commercial-health-plans-policies-compromise-patient-safety-and-raise-costs</a>

<sup>9</sup> https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0548

<sup>&</sup>lt;sup>10</sup> https://www.wsj.com/health/healthcare/u-s-launches-antitrust-investigation-of-healthcare-giant-unitedhealth-ff5a00d2

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Meanwhile, the U.S. Department of Health and Human Services recently named its first chief competition officer, noting these types of issues are its top priority in promoting greater competition in health care. Recent academic research has also highlighted troubling findings about the implications for increased vertical integration in the MA program, highlighting concerns about the reported share of spending certain vertically-integrated MA plans attribute to paying themselves through related businesses, as described in greater detail in the following section. While insurance giants have recently garnered the attention of regulators and policymakers, more scrutiny and oversight action is urgently needed to protect patients and our increasingly fragile health care delivery system.

Medical Loss Ratios and Vertical Integration in the Health Care Market. The AHA is particularly concerned about the ways in which insurers' vertical consolidation allows them to channel excessive health care dollars to their affiliated health care and data services providers at patients' expense. While the AHA supports arrangements in which an integrated system's health plan pays affiliated clinicians an appropriate rate for patient care and relies on these relationships to improve coordination of care, insurers have engaged in several abusive practices. For example, plans have directed excessive dollars to their own affiliated entities in ways that inappropriately increase health system costs. Likewise, plans have steered patients to affiliated providers to benefit the insurers financially when not in the best clinical or financial interest of the patient. These practices would not have been possible absent the explosion in vertical integration.

These practices cannot be appreciated without understanding their relationship to the Medical Loss Ratio (MLR) requirements. Vertically-integrated entities (e.g., owned by the same parent company) can effectively manipulate the MLR requirements by paying themselves. Consider this: 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. This vertical integration then enables plans to manipulate their MLR calculations by counting these extraordinary dollars paid to themselves as qualified care expenses, rather than sending those dollars back to beneficiaries or otherwise directing them toward actual health care spending.

For example, the three largest pharmacy benefit managers — CVS Caremark, Express Scripts and OptumRx — are owned by large national insurers. Pharmaceutical purchasing from PBMs is a prominent expense for these plans, and the dollars spent on such procurement are classified as qualified care expenses for MLR calculations. When

<sup>&</sup>lt;sup>11</sup> https://www.brookings.edu/articles/medicare-advantage-spending-medical-loss-ratios-and-related-businesses-an-initial-investigation/

<sup>12</sup> https://www.aha.org/aha-news/2024-04-30-aha-advertorial-unitedhealth-group-too-big-fail

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insurers purchase these PBMs, directing these large sums to the PBMs is essentially the insurers paying themselves.

Further, plans administered by vertically-integrated insurer-PBM conglomerates can implement coverage or benefit design restrictions on where their enrollees can access certain covered drug therapies or services. Unsurprisingly, PBMs have been a primary enabler of site-of-service restrictions on physician-administered specialty drugs, often sprung upon beneficiaries through mid-year plan changes. Forcing patients to switch service providers can negatively impact them clinically or financially, as well as limit access to covered services and patient choice.

Likewise, payments from a national insurer to a vertically-integrated physician also qualify as patient-care expenses under the MLR. This raises important questions about how national insurers treat their own physicians compared to physicians they do not own. For example, do they impose as stringent prior authorization requirements on their own physicians? If that spending will count toward the MLR, are insurers more likely to approve treatments by their own physicians? Are there other ways in which insurers privilege their own doctors to artificially increase patient care spending under the MLR's numerator? If so, how do those efforts harm patients, providers and the health care marketplace? Moreover, the sheer magnitude of physician practice acquisitions begs the question about what price Optum is paying for the myriad smaller physician practices it is acquiring and individual physicians it is hiring. If higher than the fair market value prices hospital systems pay, is that because the parent company UnitedHealth Group can make it up on the back end with MLR manipulation or monopolistic pricing practices? We urge HHS and other federal regulators to investigate these practices, even apart from the publicly reported DOJ antitrust investigation.

Ultimately, the use of vertical acquisitions to circumvent the goals of the MLR requirements should be a top priority for further action. They evade Congress' intent in establishing the MLR requirements and harm patients and the public.

#### Recommendations

- Increase oversight of the MLR as it relates to vertically-integrated insurer conglomerates. At the very least, the agency should increase and tighten reporting and transparency requirements to expose inappropriate or excessive payments to aligned companies that may circumvent existing MLR duties.
- Require vertically-integrated insurers to publicly report transfer prices
  associated with MA-related transactions between organizations owned by the
  same parent company (i.e., intercompany transfers) to assess whether
  above-market-level prices are being used as a means of circumventing the
  constraints that MLR rules apply to profits.

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- Investigate whether MA plans privilege their own physicians (compared to non-owned or affiliated physician groups) with respect to health plan practices such as prior authorization, timely payment or other administrative and clinical requirements in a way that could be anticompetitive.
- Study and report on the effects of growing plan consolidation and vertical integration in the MA program on quality, access to care, consumer satisfaction, member premiums, availability and use of supplemental benefits, plan profitability and MLR performance.

## 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. We recognize and appreciate CMS' guidance to MA plans in the February 2024 FAQ addressing the use of algorithms in the MA program and beginning to establish guardrails on practices that could inappropriately restrict beneficiary access to care. Building on our comments on the CY 2025 MA proposed rule, we would like to raise several observations and concerns with respect to the use of AI tools in the MA program and encourage CMS to more closely 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 plan 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 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 when 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.

CMS directly addresses this concern in guidance to MA plans in the February 2024 FAQ, which is helpful in clarifying that algorithms or software tools that are used to predict length of stay "must not be used as the basis to terminate post-acute care services; the patient must no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient's condition prior to issuing the notice of termination of services." This is an important directive which will require additional transparency and oversight to ensure appropriate use of such tools consistent with CMS guidance. We urge CMS to investigate such applications of AI tools, especially those

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used to predict length of stay or facilitate automatic denial, and whether MA enrollees are inappropriately being denied access to covered services that meet Medicare criteria using automated tools.

In addition, we reviewed CMS' February 2024 guidance on algorithms and software tools with great interest in the context that it seems to indirectly prohibit MA plans' use of AI tools, which are currently more often than not closed-source systems. CMS states that any algorithm or software tool "should only be used to ensure fidelity with the posted internal coverage criteria which has been made public under § 422.101(b)(6)(ii) ... And, predictive algorithms or software tools cannot apply other internal coverage criteria that have not been explicitly made public and adopted in compliance with the evidentiary standard in § 422.101(b)(6)." Based on our understanding of the rule, closed-source systems would not meet the criteria for public accessibility set forth in § 422.101(b)(6), which raises the question of whether MA plans can permissibly use any such automatic or algorithm-based tool that uses closed-source AI technologies.

This is one of the core issues the Office of the National Health Coordinator for Health IT (ONC) sought to address in the recently finalized Health Data, Technology and Interoperability rule (HTI-1), which seeks to advance transparency in predictive decision support tools. Consistent with the approach outlined in HTI-1, we believe clinical decision support tools, especially when used in a way that implicates beneficiary access to Medicare-covered services, should provide access to a consistent, baseline set of information about the algorithms used to facilitate decision-making or recommendations and that these pathways should be regularly assessed for fairness, appropriateness, validity, effectiveness and safety. We interpret that the CMS standards set forth in the February guidance to effectively prohibit MA plans' use of algorithms and automated software tools on the basis that existing tools do not meet the standards of public accessibility and evidence outlined in § 422.101(b)(6). We applaud the directive that internal coverage criteria must be publicly accessible and transparent, and encourage CMS to clarify its intention and interpretation of this provision with respect to closed-source AI tools.

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.

#### Recommendations

- Establishing clear and transparent standards and guidelines for the validation, implementation and continuous 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 MA plan compliance with CMS guidance requiring the individual circumstances of the patient and the recommendations of their medical team to be considered in making coverage determinations and that these important factors are not overridden by automatic or algorithm-assisted denial software.
- 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.

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- Requiring MA plans with a history of inappropriate denials to report data on the amount of time a human reviewer spends examining an adverse organizational determination prior to signing off on a denial.
- Banning compensation incentives for clinician reviewers that are based on the volume of denials they approve or uphold.

# **TIMELINESS OF INSURER PAYMENT**

In addition to challenges with inappropriate denials of care, hospitals and health systems are increasingly reporting significant financial impacts from insurers' failure to pay promptly. In fact, an AHA member survey found that 50% of hospitals and health systems reported having more than \$100 million in unpaid claims that were more than six months old. Among the 772 hospitals surveyed, these delays amounted to more than \$6.4 billion in delayed or denied claims that are more than six months old.<sup>13</sup>

These delays also add unnecessary cost and burden to the health care system, as combatting inappropriate delays and denials cost valuable time and resources, including resources needed to comply with insurer requests for additional documentation, physician peer-to-peer consultations and onerous appeal processes — and these processes may still be subject to other types of insurer audits or post-pay reviews that recoup payment to start the process all over again. Insurer processes that stagnate claim adjudication also delay billing of patient cost-sharing, resulting in patients getting bills months or even years after their care was delivered.

Given these realities and the challenges health care providers face in securing prompt payment from insurers for covered services, it is troubling that there are no universal prompt payment requirements with which insurers must comply in the MA program. Requiring that provider and plan contracts include some type of prompt payment standard is simply insufficient in the face of abusive practices designed to delay payment — rather, a universal MA prompt payment standard is needed. Indeed, most fully-insured insurance plans regulated at the state level contain some type of requirements for prompt payment for services; MA should be no exception.

#### Recommendations

 Establish a federal prompt payment standard requiring MA plans to pay contracted providers in accordance with specific timelines that are no less strict than 95% of claims paid within 30 days and imposing specific penalties for noncompliance.

<sup>&</sup>lt;sup>13</sup> https://www.aha.org/infographics/2022-11-01-survey-commercial-health-insurance-practices-delay-care-increase-costs-infographic

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• Require MA plans to report data on timely payment of claims, including but not limited to, information relating to the number and percent of claims determined to be clean and unclean; the number and percent of claims where plans request additional documentation; the timing of payments from the date of claim submission; and the percentage and average dollar amount of claims for which itemized billing is required. This information should be collected, aggregated and made publicly available for the purpose of informing additional oversight needed to ensure that MA plans comply with CMS guidance to provide coverage for services by paying for them.

#### **APPEALS PROCEDURES**

AHA members have reported concerns with how certain MA plans handle member appeals in a manner that appears designed to shield denials from independent review entity (IRE) review and CMS oversight, which underscores the importance of the recently finalized provisions to advance 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. This impedes oversight and transparency efforts related to coverage and access to Medicare benefits in the MA program.

Specifically, we have received reports from members that certain MA plans are denying member appeal rights if inpatient services have been completed and the member has no financial liability for the denial, citing that the denial is not subject to appeal. This commonly occurs for inpatient status denials where an MA plan refuses to authorize an inpatient admission. CMS has clarified in recent rulemaking that the enrollee may request a standard or expedited plan reconsideration of organizational determinations for inpatient status denials (4204-F), but we continue to hear that these appeal rights are not being honored. In some cases, it appears that plans wait until the inpatient services have been completed and set the patient liability to zero, citing service completion and lack of member financial liability as the rationale for invalidating a member's reconsideration request. We also understand that CMS' IRE for Part C reconsiderations does not accept member reconsideration requests if the service has been completed and the member cost-sharing for the denial is set to \$0, which further ensures that these types of member appeals are shielded from visibility and oversight.

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As a result, there is no recourse for a member (or for a provider) to appeal an inpatient denial and CMS nor its contractors have any visibility in these types of denials if the appeals are invalidated and no notice of dismissal is provided as required by federal rules. And certain MA plans appear to be exploiting this loophole to avoid payment for services where in-network coverage and payment are required. In effect, these plan practices 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.

Furthermore, these plan practices also serve to ensure that certain member appeals do not count against the plan for the purpose of its star rating calculation, which considers appeal measures. If the member appeals are invalidated by the plan and not reported to CMS' IRE, it is as if they don't exist for the purpose of calculating the star rating appeals measures. 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. It also serves to further enrich MA plans that are shirking their responsibility to pay for the basic benefit of inpatient care, circumventing appeal rights for that care and then being financially rewarded for their performance on appeals measures that do not reflect the full scope of reconsideration requests.

#### Recommendations

- Increase oversight and monitoring of plan compliance with the reporting of appeal measures to ensure accurate reporting, transparency into appeal procedures and findings, and calculation of star ratings.
- Clarify that members may appeal any adverse organizational determination within the applicable regulatory appeal timeframes, even if services are completed and the MA sets patient liability at \$0.
- Allow contracted providers to appeal an adverse organizational determination on their own behalf instead of only permitting the member to exercise this right. This right to appeal would not address pricing of the item or service only the question of it is a covered Medicare benefit.
- Direct the CMS IRE for Part C reconsiderations to accept member reconsideration requests even if the service is completed and the MA plan has set member cost-sharing for denied services to \$0.

# IMPLICATIONS OF INCREASING MEDICARE ADVANTAGE ENROLLMENT

As CMS is well aware, MA enrollment has been increasing for two decades. In 2023, for the first time, more than half of Medicare beneficiaries were enrolled in the program —

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30.8 million people, or 51%t of the eligible Medicare population.<sup>14</sup> This shift raises many policy questions, including about how it will affect Traditional Medicare. We have begun to analyze this question and want to ensure that the agency is aware of our work. While it is, of course, not comprehensive, we discuss examples of key implications below and would appreciate continuing to partner with the agency on this issue.

Medicare Quality Measurement Programs. The AHA recommends that CMS consider how the growth in MA could affect its ability to implement its quality reporting and value programs, as well as the reliability and accuracy of the measures within them. Every hospital quality reporting and performance program includes at least some measures that are calculated based on only Traditional Medicare data. The accuracy of these measures — and the adequacy of their risk adjustment models for comparing hospital performance — depend on having sufficient volumes of patients to include in the measures. Lower proportions of Traditional Medicare patients could distort evaluation of hospitals' performance; this is particularly true to the extent that Traditional Medicare retains the sickest or highest need beneficiaries, including most in the last year of life. Hospital quality measurement programs that depend heavily on Traditional Medicare data include:

- The Hospital Readmissions Reduction Program (HRRP), in which all measures are calculated using only Traditional Medicare claims data. The HRRP can penalize hospitals up to 3% of their inpatient PPS payments based on performance.
- The Hospital Value-based Purchasing Program (HVBP), in which half of a
  hospital's score is based on mortality, complications and Medicare payment
  measures calculated using only Traditional Medicare data. The budget-neutral
  HVBP program withholds 2% of inpatient PPS payments and redistributes it to
  hospitals based on their quality scores.
- Hospital Star Ratings, in which approximately half of a hospital's score is based on Traditional Medicare claims-based readmissions, mortality and complications measures.

In some cases, CMS has begun to explore approaches to including MA patients in measure calculations. We encourage the agency to ensure any algorithms for including MA patients are carefully tested for accuracy and validity. We also encourage CMS to ensure that the inclusion of MA patients does not inadvertently lead to distortions in which a hospital's performance is unduly affected by the proportions of MA patients included in the programs.

<sup>&</sup>lt;sup>14</sup> https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/

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Prospective Payment System (PPS) Accuracy and Stability. Under the various Traditional Medicare PPSs, payments are calculated using the most recently available data on providers' costs of treating different types of beneficiary cases. As such, on average, payments are designed to cover the cost of treatment. However, as beneficiaries move from Traditional Medicare to MA, these rates will, by definition, be based on fewer and fewer cases, which has the potential to destabilize the PPSs. Also concerning is that these rates are used to calculate the MA benchmarks. If current trends continue, these benchmarks will affect most Medicare beneficiaries but will be based on the incurred costs of a minority, likely unrepresentative, sample of beneficiaries.

A case example can be found by examining the LTCH PPS. The volume of standard rate LTCH discharges has fallen by over 40% from FY 2016 to FY 2022. 15 While these decreases are not primarily due to increasing MA enrollment, it is certainly a contributing factor. And, regardless of the cause, important lessons can be drawn from the destabilization the LTCH PPS has undergone with such a significant decrease in volume. For example, the remaining cases are becoming significantly consolidated into a relatively small number of LTCH diagnosis-related groups (DRGs). Specifically, 20 groups account for almost 80% of LTCH standard rate cases, and 10 account for almost 70% of cases. 16 Within these cases, however, there is great variation in patient severity and therefore in actual cost. The variation within DRG costs for these cases has led to a much higher than typical number of them qualifying for outlier payments because the DRG payment is not sufficient.

The fact that many more cases than usual are qualifying for outlier payments has, in turn, caused the outlier fixed-loss amount to skyrocket. Specifically, it has increased by a staggering 265%, from \$16,423 in FY 2016 to \$59,873 in FY 2024.<sup>17</sup> This means that the financial loss that LTCHs must take on before the outlier policy provides relief has more than tripled. Indeed, due to the rise in the fixed-loss amount, the total additional loss that the LTCH field must incur before seeing financial relief through additional outlier payments is approximately \$250 million annually — and this is all before the agency's recent proposal to increase the fixed-loss amount by another 52% to \$90,921 for FY 2025. These staggering financial losses are having a hugely detrimental impact on LTCHs, particularly because they are spread among a significantly reduced number of cases. We continue to recommend that CMS and Congress take steps to ensure that LTCHs can continue caring for their beneficiaries and communities.<sup>18</sup> This includes CMS reverting to a market-basket based methodology for calculating the outlier fixed-

<sup>18</sup> Ibid.

<sup>&</sup>lt;sup>15</sup> https://www.aha.org/white-papers/2023-12-29-white-paper-medicares-ltch-outlier-policy-needs-reforms-protect-extremely-ill-beneficiaries

<sup>&</sup>lt;sup>16</sup> AHA analysis of FY 2022 LTCH Medicare Provider Analysis and Review files, March update.

<sup>&</sup>lt;sup>17</sup> https://www.aha.org/white-papers/2023-12-29-white-paper-medicares-ltch-outlier-policy-needs-reforms-protect-extremely-ill-beneficiaries

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loss amount, as well as more broadly initiating an analysis of LTCH cases' cost variation within payment groups to determine whether refinements to improve overall payment accuracy are needed.

While discharges under other PPSs have not declined to the extent of those under the LTCH PPS, similar trends still exist, and one can still surmise that similar issues will arise. For example, discharges under the inpatient PPS decreased by 28% from 2015 through 2022<sup>19</sup> and discharges under the SNF PPS decreased by 25% from 2015 through 2021.<sup>20</sup> Increasing MA enrollment is, of course, not the only cause of these trends, but it has certainly contributed.

Payment Adequacy. Under a statutory "non-interference" clause, MA plans are not required to follow Traditional Medicare payment rules and are generally free to negotiate payment rates with providers if the resulting costs meet actuarial equivalence requirements. However, this requirement, coupled with the steady growth in MA enrollment, poses an increasing threat to hospitals. For example, from 2010 to 2023, MA enrollment quadrupled in rural counties compared to enrollments doubling elsewhere. As enrollment continues to grow, a greater portion of rural hospitals' revenues will be at the discretion of MA plans' payment terms, which are often below cost and include plan requirements that add to their administrative costs and decrease revenue due to coverage denials. For example, our rural hospitals have reported that even when they have a contracted rate of 101% of the cost of care, a plan may refuse to "settle up" to this rate after the rate year concludes. That is, the plan pays the hospital an interim rate that is below their contracted rate of 101% of cost, but then will not reconcile this interim rate with the contracted rate, resulting in them being paid less than the cost of care.

Behaviors such as these jeopardize the sustainability of rural providers and their ability to serve their communities. For example, 147 rural hospitals have either closed completely or ceased providing hospital care since 2010.<sup>22</sup> In addition, workforce challenges are substantial, particularly because these areas are often attempting to recruit and retain practitioners without adequate capital. For example, recent research finds that 65% of rural counties do not have a psychiatrist; 47% do not have a psychologist; and 81% do not have a psychiatric nurse practitioner.<sup>23</sup> In addition, the

<sup>&</sup>lt;sup>19</sup> AHA analysis of 2015-2022 national MedPAR files, March updates.

<sup>20</sup> https://www.kff.org/medicare/state-indicator/skilled-nursing-facilities/?activeTab=graph&currentTimeframe=0&startTimeframe=7&selectedDistributions=total-covered-admissions&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D.

<sup>&</sup>lt;sup>21</sup> https://www.kff.org/medicare/issue-brief/medicare-advantage-enrollment-plan-availability-and-premiums-in-rural-areas/

<sup>22</sup> https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.

<sup>&</sup>lt;sup>23</sup> https://www.aha.org/system/files/media/file/2022/09/rural-hospital-closures-threaten-access-report.pdf.

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number of hospitals providing obstetric services in rural areas has declined — over half of rural counties don't have a hospital that provides these services. This was particularly prevalent in low-income areas and is associated with problems such as premature births.<sup>24</sup>

As another example, the growth of MA has also contributed to financial instability for LTCHs. Specifically, MA plans routinely and inappropriately deny beneficiaries access to LTCH care.<sup>25</sup> Indeed, while about half of Medicare beneficiaries were enrolled in MA in 2022, only about 31% of LTCHs' Medicare discharges were for MA beneficiaries.<sup>26</sup> Further, those beneficiaries that are allowed access to LTCH care are often of the highest acuity.<sup>27</sup> Indeed, trends such as this have led CMS to take specific steps to ensure that MA plans do not restrict access to covered benefits such as LTCH care.<sup>28</sup>

More detailed examples also exist. For example, Medicare makes direct graduate medical education (DGME) payments for beneficiaries' inpatient hospital utilization. Generally, these payments are based on a hospital's per resident amount (PRA), a weighted number of full-time equivalent (FTE) residents, and the hospital's Medicare share of total inpatient days. Although the hospital's weighted FTE residents is subject to a cap, its PRA is updated for inflation, so DGME payments per resident increase over time. Medicare also makes DGME payments for MA beneficiaries' inpatient hospital utilization. While these payments will reflect growth in the MA utilization, they are reduced to finance reasonable cost payments to hospitals receiving nursing and allied health (NAH) education payment based on their MA utilization.

Relatedly, Medicare also makes payments for Traditional Medicare beneficiaries' share of hospital costs incurred in connection with approved education activities, including NAH programs. In addition, as mentioned, it makes payments for MA beneficiaries' share of NAH program costs, However, these MA NAH payments are subject to a dollar amount cap of \$60 million annually, an amount which not been updated since 1999. This cap is routinely reached each year. Thus, as beneficiaries move from Traditional Medicare to MA, hospitals' Traditional Medicare NAH payments are decreasing, but their MA NAH payments are not increasing (proportionately or otherwise).

<sup>&</sup>lt;sup>24</sup> https://www.gao.gov/products/gao-23-105515

<sup>&</sup>lt;sup>25</sup> HHS, Office of Inspector General (OIG); Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care (April 2022) (https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf).

<sup>&</sup>lt;sup>26</sup> Data from Strata Decision Technology, a health care technology and consulting firm (https://www.stratadecision.com/company/).

<sup>&</sup>lt;sup>27</sup> https://cdn.ymaws.com/nalth.site-

<sup>&</sup>lt;u>ym.com/resource/resmgr/public/researchbriefs&whitepapers/2021/200226.1\_nalth\_policy\_p03.pdf</u>

28 Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program; 88 Fed. Reg. 22,120 (April 12, 2023).

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These two limitations are eroding Medicare's support of GME. This is very troublesome given that hospitals and health systems already face mounting and critical physician shortages (estimated by the Association of American Medical Colleges to reach 124,000 physicians by 2033) that will jeopardize access to care in communities across the nation. These and other clinician shortages — combined with an aging population, a rise in chronic diseases and behavioral health conditions, physician burnout from the pandemic, and state-of-the-art care delivery advancements — all underscore the need for Medicare to at the very least maintain its GME funding. Without this support, it will be difficult to impossible to adequately prepare America's health care workforce for the health system of the future and ensure continued access to care.

In addition, under the inpatient PPS, hospitals that treat a disproportionate share of certain low-income patients receive additional payments intended to offset the financial effects of treating these patients. These disproportionate share hospital (DSH) payments are included in MA benchmarks with the implicit expectation that they will be passed along to hospitals as appropriate. However, it is unclear if they are, especially when negotiated plan payments are below hospitals' costs. What is clear is that Traditional Medicare DSH payments are decreasing as Traditional Medicare inpatient PPS hospital discharges decline. If these funds are not paid from the MA side, it will result in yet another reimbursement cut to hospitals.

Lastly, growing MA enrollment is not only resulting in increasingly inadequate hospital reimbursement but also in much higher hospital administrative costs. This is a result of much higher use of utilization management programs, such as prior authorization and appeals, which require substantial staff time. It is also a result of variation in rules and processes that require hospitals to license unique (and often duplicative) software and tools to comply with different health plan policies.

Alternative Payment Models (APMs). Another area of Traditional Medicare policy affected by the shift of beneficiaries to MA is APMs. CMS tests payment and delivery models with the purpose of reducing program expenditures while still preserving or enhancing the quality of care. As such, it analyzes models' impacts on Medicare spending. However, as fewer beneficiaries are enrolled in Traditional Medicare, detecting statistically significant changes in spending will become more and more difficult. Specifically, it will require greater proportions of the population to participate, and the detectable reductions will be of a much smaller dollar amount. For example, CMMI recently proposed implementing a mandatory bundled payment model for hospitals across five service lines.<sup>29</sup> Even under current Traditional Medicare enrollment, it would require a full quarter of eligible geographic areas to participate in the model in order to have an adequate sample size for detecting reasonably notable

<sup>&</sup>lt;sup>29</sup> <u>https://public-inspection.federalregister.gov/2024-07567.pdf</u>

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changes in spending. Adequate participation and savings rates will only be more difficult to achieve as Traditional Medicare enrollment declines.

In addition, APMs such as the bundled payment model described above evaluate whether shared savings were achieved by setting benchmarks relative to Traditional Medicare spending. As the population of Traditional Medicare decreases, these benchmarks themselves will be based on a declining number of beneficiaries and may very well be distorted.

#### Recommendations

- Consider and analyze changes in the Medicare program, including IPPS
  policies and performance incentives, resulting from continued growth in MA
  enrollment and lower Traditional Medicare enrollment, such as implications
  for patient access, payment adequacy, and quality measurement.
- Ensure cost-based reimbursement for CAHs in the MA program consistent with their special designation under Traditional Medicare, which provides payment of 101% of eligible CAH costs.
- Ensure payment adequacy for LTCHs in the future as MA continues to grow and they encounter other evolving changes in the Medicare program. This includes, reverting to a market-based methodology for calculating the LTCH PPS outlier fixed-loss amount, as well as more broadly initiating an analysis of LTCH cases' cost variation within payment groups to determine whether refinements to improve overall payment accuracy are needed.