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Advancing Health in America

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February 13, 2022

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

Re: CMS 4201-P, Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners — including more than 270,000 affiliated physicians, two million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule for policy and technical changes to the Medicare Advantage (MA) program in contract year 2024.

The proposed rule includes important protections for MA beneficiaries and clarifications for Medicare Advantage Organizations (MAOs) that will improve how coverage works for enrollees, promote more timely access to care, strengthen behavioral health provider networks, help patients understand their Medicare coverage options and reduce the administrative burden of health plan requirements on health care providers. **The AHA strongly supports the proposed changes intended to strengthen consumer protections and oversight of MAOs, which are critical and urgently needed, and we encourage the agency to expeditiously finalize these important program updates.** We also share CMS' strong commitment to advancing health equity and improving access to behavioral health services, and thus support the proposals designed to better address social determinants of health, ensure culturally competent care and ensure MAOs maintain adequate behavioral health provider networks.

Hospitals and health systems nationwide are increasingly concerned about certain MAO policies that restrict or delay patient access to care, while adding cost and burden to the

system. These include misuse of utilization management programs, inappropriate denial of medically necessary services that would be covered by Traditional Medicare, requirements for unreasonable levels of documentation to demonstrate clinical appropriateness, inadequate provider networks to ensure patient access and unilateral restrictions in health plan coverage in the middle of a contract year, among others. These practices harm the health of Medicare beneficiaries and are a major driver of health care worker burnout, while also adding billions of wasted dollars to the health care system.[1] In response to these persistent challenges, we commend CMS for its proposals designed to increase oversight and accountability of health plans and protect patients, and we urge these changes be finalized.

We especially appreciate CMS' proposals and clarifications to align and ensure greater equity between Traditional Medicare and the MA program and to explicitly codify that MAOs cannot indiscriminately deny services that would have been covered under Traditional Medicare. **We believe the proposed changes will go a long way in ensuring that Medicare beneficiaries have equal access to medically necessary care and consumer protections and that those enrolled in MA will not continue to be unfairly subjected to more restrictive rules and requirements.**

While these proposals are all critical steps forward in advancing patient access and holding MAOs accountable for adhering to federal rules, we believe a heightened level of enforcement and oversight is needed to facilitate meaningful change. Accordingly, once finalized, **we urge the agency to conduct rigorous oversight to enforce the policies and safeguards included in the rule and to ensure that appropriate action is taken in response to violations of CMS rules.**

In the following sections we enumerate our support for the health plan oversight provisions included in the proposed rule, underscoring the importance of these changes for patients and providers and the need for deliberate enforcement. We also discuss several opportunities to expand oversight and strengthen key provisions and protections. Finally, we offer concerns regarding the proposed changes to the rules governing overpayments, and specifically, the elimination of the six-month investigation period that providers currently have to quantify overpayments before the obligation to repay is triggered. **We urge the agency to not impose an unrealistically strict 60-day deadline on hospitals and health systems to return overpayments once they are on notice of an overpayment.**

Finally, although we recognize that the proposed provisions are applicable to MAOs that contract for the 2024 calendar year, we encourage CMS to explore use of existing authority to mitigate negative impacts associated with the end of the COVID-19 public health emergency (PHE) on May 11th and the expiration of several key waiver flexibilities intended to alleviate capacity strains on hospitals. As hospitals and health

[1] 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

systems prepare for a new post-PHE normal, while also weathering chronic and persistent workforce shortages, we believe these proposed health plan oversight provisions will be important in providing both short-term and long-term relief to the health care delivery system. In this context, we encourage the agency to expeditiously finalize the proposed rule and explore opportunities to provide immediate, short-term relief to coincide with the PHE expiration and unwinding.

Our comprehensive comments follow, along with an appendix of patient case examples (**Appendix A**), illustrating the impact of inappropriate delays and denials on MA beneficiaries and underscoring the need to finalize the proposed patient protections.

PRIOR AUTHORIZATION AND MEDICAL NECESSITY DETERMINATIONS

The AHA commends CMS for its commitment to reforming MAO prior authorizations and medical necessity policies, which often create a significant impediment to the delivery of efficient, timely — and therefore high-quality — patient care. Although initially designed to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, many MAOs apply prior authorization requirements in ways that can create dangerous delays in care, contribute to clinician burnout and drive up costs for the health care system. The widespread use of prior authorization, which does not exist to nearly the same extent in Traditional Medicare, and the application of more restrictive rules and criteria in MA has been a pervasive challenge for patients and providers — and has created coverage and access inequities between Medicare beneficiaries. The AHA urges CMS to finalize these important regulations and offers the following comments on its specific provisions.

Alignment of Medical Necessity Criteria between Traditional Medicare and MA

The MA program was intended to provide beneficiaries with coverage of an equivalent set of services to Traditional Medicare with a level of access that is no less favorable, but that aim is not consistently achieved. **The AHA applauds CMS' proposal to limit MAOs from adopting more restrictive rules than Traditional Medicare, seeking to ensure MAOs provide access to an equivalent set of covered services as intended.** Specifically, CMS proposes that plans can only create internal medical necessity criteria "when there is no applicable coverage criteria in Medicare statute, regulation, NCD [national coverage determination], or LCD [local coverage determination]," and that such criteria must be "based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available to CMS, enrollees, and providers."

Eliminating MAO flexibility to apply differential and opaque criteria for medical necessity reviews — which today are often inconsistent with Medicare coverage rules — would be significantly beneficial for patients and their providers. Currently, MAOs often classify their medical necessity criteria as proprietary and do not share specifics with external parties, resulting in a "black box" for providers attempting to determine whether a

service will be approved. This lack of transparency is a frequent reason that prior authorization and claims are delayed or denied. Leaving providers in the dark about what documentation they must provide results in extensive back and forth between providers and plans, which only serves to delay care and unnecessarily burden clinical staff with resource-intensive paperwork.

Furthermore, use of more restrictive internal MAO medical necessity criteria has resulted in coverage inequities between Medicare beneficiaries and a growing volume of inappropriate denials, as evidenced by an April 2022 Department of Health and Human Services Office of the Inspector General (HHS-OIG) report.[2] The HHS-OIG report found that 13% of MA prior authorization denials and 18% of MA payment denials that were reviewed met Medicare coverage rules and should have been granted. In addition, the report identified a range of hospital-level services that are frequently restricted or inappropriately denied by MAOs, including institutional post-acute care (PAC) admissions, inpatient hospital admissions, advanced imaging services and injections, as well as lab tests, radiation treatment and therapy services, among others.

Despite existing CMS rules precluding MAOs from using clinical criteria that are more restrictive than Traditional Medicare, the experience of hospitals and health systems nationwide, paired with government oversight reports like those from the HHS-OIG, clearly show that some MAOs are routinely doing exactly that. Hospital inpatient admission is one area in which plans often administer proprietary medical necessity criteria that is inconsistent with Medicare coverage rules. Inconsistent and more restrictive plan criteria for inpatient admissions frequently leads to uncertainty for providers and patients — whose medically justified inpatient stays are often denied or retroactively downgraded to observation stays, even in situations where the clinical necessity for the admission far exceeds plan requirements. We provide in Appendix A several case examples of MAOs applying more restrictive criteria for inpatient admissions and describe the resulting impact on patients.

Such inappropriate denials of necessary inpatient coverage would be prohibited under CMS' proposal, which explicitly reiterates that coverage of inpatient admissions, skilled nursing facility (SNF) care, home health services and inpatient rehabilitation facilities (IRF) are basic Medicare benefits for which MAOs may not utilize proprietary medical necessity criteria. **We urge CMS to finalize these important provisions codifying that MAOs must provide access to care for basic benefits in a way that is consistent with, and no more restrictive than, Traditional Medicare.** We also discuss the apparent exclusion of long-term acute hospitals (LTCHs) in a subsequent section on PAC issues and recommend LTCHs be explicitly included in these protections as well.

[2] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

The proposed rule also provides important clarifications to explicitly disallow other strategies MAOs may use to steer patients inappropriately to lower cost tests or treatments before they will cover the medically necessary service ordered by the patient's doctor. For example, a plan may require a less expensive imaging test such as an X-ray before authorizing a computerized tomography (CT) scan, even if the physician needs a CT scan to appropriately diagnose or manage a patient's condition. As a result, the patient may need to undergo an unnecessary scan to satisfy their insurer's policy before being able to access the test they actually needed — even though it is a covered service. This delays appropriate treatment and increases cost to the health care system. In response to such plan policies, we commend CMS' proposed approach, which would prohibit utilization management processes that require another item or service to be furnished prior to the patient receiving the requested item or service. These rules would prevent patients from having to receive unnecessary care — which was not recommended by their doctor — to receive MAO coverage. For these reasons, and in support of CMS' intent to better align Traditional Medicare and MA, **AHA urges CMS to finalize the proposals in § 422.101 to ensure that MAO beneficiaries receive access to the same basic benefits, reviewed under the same criteria, as Traditional Medicare beneficiaries**.

Further Clarity to Support Understanding and Compliance

In the face of compelling evidence that certain MAOs have historically circumvented federal rules in applying overly restrictive medical necessity criteria, the **AHA recommends that CMS adopt more specific language regarding the Traditional Medicare rules that MAOs are required to follow.**

Two-Midnight Rule. We interpret that the reiteration of inpatient admissions as a basic benefit and the requirement that MAOs cover basic benefits in a fashion that is no more restrictive than Traditional Medicare means that MAOs must follow the Two-Midnight rule and adhere to the Inpatient Only List. This would effectively prevent MAOs from downgrading inpatient hospitals stays that exceed two midnights to observation status as raised in the preceding examples — a practice that effectively applies a more restrictive set of criteria to an inpatient admission. **It would enhance clarity and adherence if CMS were to explicitly state that MAOs must follow the Two-Midnight rule as opposed to leaving this to interpretation**. In this way, we encourage CMS to offer greater specificity and delineate the specific rules that MAOs must follow pursuant to Traditional Medicare coverage rules where possible.

Sepsis. We believe that additional clarification and restatement is warranted regarding the limitations on MAO use of internal criteria for sepsis care. Many MAOs require providers to meet sepsis criteria beyond the CMS-recognized Sepsis-2 requirements, frequently leading to inappropriate denials and time-consuming appeals processes. While the AHA believes that the proposed rules are intended to apply to these scenarios and service areas, many of our members have expressed concerns about the potential for MAOs to misapply these provisions for sepsis criteria in particular, given their

extended history of doing so. Therefore, in order to prevent any potential misunderstandings and improve the likelihood of adherence, **we recommend that CMS should enhance regulatory language to specifically address sepsis, explicitly directing plans to comply with Medicare criteria and coverage rules for sepsis-related services — and prohibiting the use of all internal MAO criteria**.

Initial Medical Necessity Reviews. To ensure that the proposed rule achieves the intended patient protections, the AHA urges CMS to clarify and require plans to update their criteria and processes used in their *initial* medical necessity reviews, rather than through appeals processes after the fact. Too frequently, providers are forced to engage in lengthy and resource-intensive appeals processes before MAOs will properly apply applicable criteria, as highlighted by a September 2018 HHS-OIG report.[3] The report found that MAOs overturned more than 75% of their own medical necessity denials when appealed. Unfortunately for patients and providers, it is often not practical to delay care while appeals are adjudicated, and the system is highly susceptible to abuse if MAOs are able to deny large volumes of care up front only to overturn them later once time and resources have been expended in appeals. This is especially troubling given the relatively low percentage of denials that are ultimately appealed — a reality that certain insurers may count on. Therefore, to ensure that patients receive necessary care in a timely manner, **the AHA recommends that CMS proactively clarify that plans must update and apply medical necessity criteria consistent with this rule to their *initial* determinations; not only to subsequent reviews occurring during the appeals process, when many denials are ultimately overturned after the fact.**

Finally, CMS also indicates in the preamble that, "we expect MA organizations to make medically necessary decisions in a manner that most favorably provides access to services for beneficiaries." We agree and support CMS' direction to MAOs in this context and recommend that this expectation be extrapolated beyond the preamble and converted to a more specific directive for MAOs in the regulatory text**. In other words, the expectation to make medical necessity decisions in a way that most favorably provides access should be a stated regulatory requirement for MAOs as opposed to a statement of CMS' intent.**

Relevant Medical Expertise to Review Medical Necessity Determinations

AHA commends CMS' proposed update to § 422.566(d), which seeks to ensure appropriate personnel make medical necessity determinations for MA beneficiaries. Patients should be able to rely on the expert judgment of their clinicians, absent proposed care being clinically invalid or inconsistent with CMS rules. In order to ensure that denials are made based on relevant and applicable medical expertise, reviewing clinicians must have appropriate training in the field of medicine for the service being requested.

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[3] https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf

Peer-to-peer Discussions. Hospitals and health systems frequently report that health plan reviewers without applicable expertise in the requested service discipline are issuing denials for medically necessary patient care. This is especially common for PAC admissions where a clinician without expertise in any rehabilitative discipline overrules the judgement of a treating physician who specializes in rehabilitative care. This problematic dynamic plays out across a number of medical specialties. **We appreciate CMS' recognition of this issue in proposing updates to the qualifications of the reviewing clinician and urge CMS to specify that these rules apply to peer-to-peer discussions in addition to prior authorization reviews.** Furthermore, the AHA interprets that the provisions requiring the health plan clinician to have relevant medical expertise in the requested service area apply to both standard and expedited organization determinations, but this is not explicitly stated in the rule. Given the critical nature of expedited reviews for patients requiring exceedingly urgent care, **we request that CMS clarify that this requirement also applies to expedited reviews in addition to standard reviews, thereby ensuring timely access to appropriate care as determined by a qualified medical practitioner.**

We expect that to comply with these provisions MAOs may be required to contract with additional physician reviewers to comply and are concerned that plans may retain too much discretion to determine what constitutes "appropriate expertise" as written, potentially allowing them to retain existing protocols without making meaningful changes. Specifically, the proposed rule specifies that MAOs "will have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition." While we recognize that workforce shortages are a perpetual challenge and some flexibility may be needed, we believe the case-by-case exception offers too much discretion for MAOs to define appropriate expertise.

To ensure that the proposed provisions have the intended effect, **we recommend that CMS require MAOs to develop a list of services which require prior authorization for their MA products and delineate the specific provider types and specialties, noting requisite training and rationale, who will be conducting medical necessity reviews, prior authorization reviews or peer-to-peer consults for those services**. **MAOs should be required to share the list with their contracted providers at the beginning of every contract year.** This would provide a level of transparency and accountability in ensuring that clinicians with appropriate qualifications are making organizational determinations as a matter of MAO standard operating procedures without adoption of a more restrictive or unreasonable standard. We also suggest the Utilization Management Committee (UMC), which we discuss in the following section, should play a prominent role in developing the list of provider types and specialties who will be making these organizational determinations to ensure compliance with these provisions.

Utilization Management Committee. To ensure that plan policies are valid and adequately reviewed with appropriate oversight, the proposed rule requires MAOs to

establish a UMC led by the plan's medical director. This committee would be required to conduct an annual review of plan prior authorization and utilization management (UM) polices to ensure compliance with Medicare rules and consistency with current clinical guidelines. The AHA strongly supports the establishment of a required UMC to increase oversight of UM programs and examination of the results of these policies on patient access to care. However, we feel strongly that the increased internal MAO oversight created by this requirement is *not* a substitute for external oversight or CMS enforcement. We discuss our specific recommendations around enforcement in a subsequent section.

CMS solicits comment on several areas about the structure and functions of the UMC including the level of consultation with contracted providers, communication about UM policies with providers and what role the UMC should play in ensuring organizational determinations are consistent with stated policies. We offer the following comments and recommendations in response.

- **The duties of the UMC should be expanded to include oversight of all internal coverage criteria used by the MAO, in addition to UM policies.** Internal coverage criteria would not likely be characterized as a UM policy and therefore would not be subject to review by the UMC — but as CMS notes, MAO coverage criteria could be used to limit patient access to covered services and should therefore be subject to this additional layer of oversight.
- **The UMC should have an active and ongoing oversight role in ensuring that decisions made by an MAO throughout the year are consistent with the final, approved practice guidelines and UM policies.** Meaningful oversight is not only ensuring that the rules are appropriate, but also making sure the rules are followed in practice. Charging the UMC with conducting retroactive review of organizational determinations throughout the year and assessing whether the approved practice guidelines and UM policies were followed is important to ensure the processes are working properly and that Medicare rules are being followed in practice, not just on paper.
- **The UMC should be explicitly required to ensure that applicable UM policies and procedures are developed in consultation with contracted providers.** Currently MAOs are required to consult with contracted providers regarding the organization's medical policy, quality improvement programs and medical management procedures, so it is logical and advisable for MAOs to also be required to consult with contracted providers on the development of utilization management policies. CMS may want to consider explicitly requiring that a seat on the UMC be filled by a clinician from a contracted provider organization.
- **The UMC should have a more explicit role in implementing existing requirements that MAOs communicate information about practice guidelines and UM policies to providers and enrollees.** Hospitals and health systems often report that changes to MAO utilization management protocols are

made mid-contract year and without notice to contracted providers. Often, such changes are posted on an MAO website, requiring provider staff to constantly monitor MAO websites for impending changes that are otherwise unannounced. Additional oversight and accountability for ensuring such changes are communicated appropriately to affected parties would be a helpful improvement over current practice and an appropriate charge for a UMC.

- **The UMC should include required representation from specific types of providers with expertise in relevant medical disciplines with a history of inappropriate denials.** Specifically, CMS should consider explicitly requiring representation from a physician with training and expertise in medical rehabilitation and one with such expertise in behavioral health.
- **The regulatory text should explicitly clarify that the UMC is involved in the development of utilization management policies**, as opposed to only the review and approval of such policies.
- **The UMC should be required to have an active and ongoing role throughout the year as opposed to only reviewing criteria on an annual basis.** CMS may want to consider requiring the UMC to conduct quarterly or bi-annual reviews of UM policies and programs and their effects on organizational determinations, patient access and clinical validity.

Site of Service Protections

The AHA commends CMS for the inclusion of provisions designed to protect patients from unnecessary site of service restrictions. Specifically, CMS states multiple times in the preamble that when care could plausibly be provided "in more than one way or in more than one type of setting," an MAO may not impose its choice of site of care and deny the request on those grounds if there is no basis for such restriction in Traditional Medicare. Protecting patients from inappropriate site of service restrictions is imperative; such changes can impede patient access and delay care, especially when adopted mid-plan year or applied to critically ill or complex patient populations. To ensure that the regulations truly create such protection, **we encourage CMS to establish more explicitly a clearly stated site of service limitation in the regulatory text (as opposed to the preamble) that directly prohibits MAOs from adopting policies which restrict the site(s) where a covered services can be delivered when there is no basis for that restriction in Traditional Medicare.**

Continuity of Care

The AHA urges CMS to finalize its proposed patient protections for continuity of care. As proposed, CMS would require prior authorizations to be valid for the entirety of a prescribed treatment and require plans to honor existing prior authorizations for no less than 90 days of patient enrollment. This would preclude the need for additional prior authorizations for each episode of care in a series of prescribed treatments, such as a regimen of chemotherapy, which can delay or interrupt ongoing treatments

unnecessarily. Regulations eliminating plan use of repetitive mid-treatment prior authorizations would benefit particularly vulnerable patients, as illustrated by case examples in Appendix A. As a result, the **AHA commends CMS for codifying these important patient protections to support continuity of care and stresses the importance of finalizing these proposals.**

Post-Stabilization Services

Existing CMS regulations state that MAOs are financially responsible for post-stabilization services related to an emergency medical condition and must apply a rapid turnaround time for prior authorization responses in such cases. Specifically, § 422.113(c) requires that post-stabilization care that is administered to maintain, improve or resolve the enrollee's stabilized condition is the responsibility of the MAO *even when not pre-approved* by the MAO *if the MAO does not respond to the pre-approval within one hour or cannot be contacted*. In other words, there is an existing regulatory requirement for a one-hour turnaround time on MAO approvals for post-stabilization care *and* a requirement that MAOs be financially responsible for this care. We believe this provision is routinely being ignored and circumvented. Hospitals and health systems report that MAOs routinely misapply organizational determination rules and timeframes specified in § 422.113(c), which commonly results in retroactive denials of post-stabilization services related to an emergency medical condition, despite explicit regulatory requirements binding MAOs to cover these services even when not pre-approved. While the regulatory text is already decisive on this topic, we seek to highlight this issue as an example of where certain MAO practices do not comply with CMS rules, and to recommend that CMS conduct additional oversight and enforcement to ensure adherence with these existing rules.

IMPROVING ACCESS TO BEHAVIORAL HEALTH SERVICES

The AHA applauds CMS for its proposals to expand access to behavioral health services in the MA program. Many of these provisions are precisely what the AHA and our member hospitals and health systems have advocated for, along with other stakeholders, in response to CMS proposals and requests for information (RFIs) issued over the past two years. Coupled with other provisions in this rule, we expect the additional network adequacy requirements and clarifications to reduce the volume of delays and denials for behavioral health care coverage under MA and improve access to critical services.

Additions to Behavioral Health Specialty Provider Type Requirements for Network Adequacy

The AHA supports CMS' proposal to add clinical psychologists (CP), licensed clinical social workers (LCSW) and prescribers of medication for opioid use disorder (MOUD) as specialty provider types for which there are specific minimum network standards, in addition to the current requirements to demonstrate adequate inclusion of psychiatry

providers and inpatient psychiatric facilities. Behavioral health care services involve a wide continuum of providers, facilities and settings, all of which must be incorporated into insurance coverage to sufficiently meet specialized patient and community needs. Furthermore, by explicitly evaluating MA networks for adequate supplies of CPs, LCSWs and MOUD prescribers — rather than including a nebulous category of general behavioral health providers — CMS will be better equipped to evaluate the completeness of a plan network and hold MAOs accountable for meeting beneficiaries' needs more precisely.

Shortages in clinical workforce nationwide mean that there are logistical and sometimes even financial challenges to identifying a sufficient number of clinicians of all license and degree types who are qualified to provide behavioral health care. We recognize that MAOs may face challenges in building rigorous provider networks as a result. However, this is a critical step in improving access to behavioral health care and linking patients with appropriate specialty providers in their plan's network. In addition, by expanding the types of behavioral health specialty providers required to be in-network beyond physician-level psychiatrists and inpatient psychiatric facilities, MAOs will have a wider array of qualified provider types to contract with in meeting requirements — and enrollees will have access to a broader selection of appropriately trained specialists.

The AHA also supports and provides comment on several other important provisions designed to increase beneficiary access to behavioral health services.

- **Behavioral Health Specialists Eligibility for Telehealth Credits.** CMS proposes that specified behavioral health provider types be eligible for inclusion in the calculation of the 10% "credit" MAOs can earn towards meeting time and distance standards for telehealth services. We agree that many behavioral health services may be appropriately provided via telehealth, but encourage CMS to be circumspect in how it applies this strategy. CMS should apply similar capacity standards to telehealth providers as is done with in-person providers — that is, to consider a provider to be part of the network, that provider must be accepting new patients and offer specified services within a certain number of days. Without due caution, the approach of offering "credit" towards meeting network requirements creates the potential for virtual-only providers to be overly represented in MAO networks at the expense of in-person providers who provide on-the-ground access to care.
- **Care Coordination Requirements for Behavioral Health.** The AHA also supports the proposal to require that MAOs must have programs in place to ensure continuity of care and integration of behavioral health services. People with behavioral health disorders often need ongoing support to manage their health, and disruptions in care can be devastating. This proposed change would help with care continuity and integration as part of the enrollee's care coordination plan, while limiting potential barriers or disruptions.

- **Notification of Changes in Behavioral Health Network Participation.** We also appreciate and support the proposal to include more stringent enrollee notification requirements of primary care and behavioral health provider contract terminations. These requirements should lead to MAOs providing earlier network change notifications impacting ongoing care delivery and give patients with behavioral health conditions more time to transfer care when necessitated by changes in network participation. Importantly and collectively, these provisions provide additional protections against sudden disruptions in care of ongoing behavioral health services.
- **Clarifications Regarding Emergency Behavioral Health Services.** The AHA strongly supports the proposal to add regulatory language to clarify that an "emergency medical condition," for which medical intervention must be provided without regard to prior authorization or the emergency care provider's contractual relationship with the organization, includes both physical and mental health conditions. As with physical emergencies, delays in care for mental health emergencies can result in grave harm. It is unfortunate that this clarification must be made, but this explicit regulatory directive will help diminish the stigma associated with behavioral health disorders, paving the way for improved access and greater parity between physical and mental health services.

IMPROVING ACCESS TO POST-ACUTE CARE SERVICES

AHA commends CMS for the significant steps it has taken in this proposed rule to address the serious concerns AHA and other stakeholders have raised regarding MA beneficiary access to medically necessary PAC services. As CMS knows, institutional PAC providers, including IRFs, LTCHs, 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. However, as AHA detailed to CMS most recently in response to the August 2022 RFI, MA beneficiaries are regularly and systematically denied access to covered services that are routinely provided to similarly situated Traditional Medicare beneficiaries.[4] Accordingly, the AHA strongly encourages CMS to finalize the following proposals to ensure that MA beneficiaries receive the needed PAC services to which they are entitled and offers the following comments on specific PAC-related issues.

In addition, we note that numerous waivers implemented through CMS' PHE authority have been instrumental in ensuring patients can be safely discharged in the most timely manner possible to alleviate strains on hospital capacity. These waivers, which include waiver of the IRF "60 percent rule," the SNF "3-day stay rule" and the LTCH site-neutral

[4] https://www.aha.org/lettercomment/2022-08-31-aha-comments-cms-request-information-regarding-medicare-advantage-program

payment adjustments, among others, will expire in May at the conclusion of the PHE. This will result in greater strain on both general acute care hospitals and PAC providers at a time when they are concurrently contending with historic labor shortages. Given the history of inappropriate delays and denials for PAC services and the labor-intensive activities required to appeal and secure appropriate authorizations, we anticipate these challenges will be exacerbated with the loss of certain PAC PHE flexibilities, which improved throughput to PAC sites of care over the last few years. In recognition of these challenges as we enter the post-PHE phase of the COVID-19 pandemic, we request that CMS keep PAC access at the forefront of the policy agenda and explore opportunities to provide short-term relief by finalizing the key PAC provisions, as highlighted below, and implementing them at the earliest possible date.

Coverage Criteria for Basic Benefits, Medical Necessity Determinations, Appropriate Use of Prior Authorization and Continuity of Care Requirements

As described in earlier sections, AHA strongly supports the proposed regulatory language at 42 C.F.R. § 101, § 138 and § 112, which clarify the coverage criteria that must be used for PAC admissions, the appropriate use of prior authorization and continuity of care requirements. For the reasons stated in the preamble by CMS, AHA concurs that these modifications and additions will help ensure MAOs utilize proper criteria when evaluating requests for PAC services, that MAOs use prior authorization in an appropriate manner and that the need for repeated prior authorization requests do not disrupt patient care and unduly burden providers. These updates are especially critical for PAC services, which the HHS-OIG report highlighted as one of the top service categories experiencing inappropriate denials for covered services.

Inclusion of Long-Term Care Acute Hospitals

AHA is concerned that CMS fails to include reference to LTCHs in its proposed regulatory language at § 422.101(b)(2). As presently drafted, the regulatory language cites IRFs, SNFs and HHAs, but not LTCHs. As CMS acknowledges in this section of the proposed rule, “MA organizations must cover all Part A and B benefits […] on the same conditions that items and services are furnished in Traditional Medicare.” LTCHs play a critical role for a subset of PAC beneficiaries, and importantly, are a service that is covered for Traditional Medicare beneficiaries.[5] Therefore, it is important that CMS does not exclude this PAC service by omitting it from its regulatory framework for MA coverage.

Appropriate Setting of Care

AHA applauds CMS’ expectation stated in the preamble that MA organizations “make medically necessary decisions in a manner that most favorably provides access to

[5] Congress has provided statutory criteria for Medicare coverage of LTCH care at Section 1886(m)(6)(A) of the Social Security Act.

services for beneficiaries." Similarly, CMS states multiple times in the preamble that when care could plausibly be provided "in more than one way or in more than one type of setting," an MAO may not impose its choice of site of care and deny the request on those grounds. We believe these provisions are especially important for PAC services where there are several levels of covered rehabilitation services designed to meet various clinical needs — and where MAOs can be incentivized to steer patients into lower acuity or less costly alternatives than the setting recommended by the treating physician. Indeed, this happens frequently when patients are referred to an IRF or LTCH and the MAO denies the authorization and redirects the patient to a SNF, HHA or even sometimes to home without any services.

While we appreciate the proposals in the rule that should protect against this type of inappropriate denial, including prohibiting the use of more restrictive medical necessity criteria for PAC services along with the site of service protections, we encourage CMS to explicitly establish a site of service limitation in the regulatory text (as opposed to the preamble). This stated limitation should directly prohibit MAOs from adopting policies which restrict the site(s) where a covered services can be delivered, especially for PAC services.

Network Adequacy for PAC Settings

As described above, AHA supports CMS' proposal to enhance network adequacy requirements for behavioral health services and recommends that the agency adopt similar provisions to strengthen PAC provider networks. Consistent with CMS' intention to ensure MA beneficiaries have appropriate access to basic benefits covered by Traditional Medicare, it is important that providers who deliver these basic benefits are appropriately represented in MAO networks. Current MA network adequacy rules do not include specific requirements that IRFs, LTCHs and HHAs be included in MAO 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* IRFs in-network 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.

These examples are commonplace and serve as a clear indication that more rigorous network adequacy standards are needed for PAC providers. Specifically, **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.

ENFORCEMENT AND OVERSIGHT

Throughout this proposed rule, CMS has thoughtfully addressed a wide range of stakeholder concerns about MAO policies and practices which may delay or restrict access to care. As described above, we believe these policies will go a long way to protect MA beneficiaries, increase access to care and shore up important guardrails that ensure the MA program functions as intended. However, CMS notes in several sections of the proposed rule that the provisions are restatements or codification of existing CMS policies or practices, which underscores the importance of the work ahead in the implementation phase to hold plans accountable and ensure compliance. We also recognize that many of these policies govern operational processes related to authorization, claims processing and payment, which are difficult to meaningfully oversee without rigorous oversight including plan-level data collection and reporting, regular auditing, pathways for stakeholders to report suspected violations, and penalties for non-compliance. Each of these elements will be critical in ensuring these important changes become standard operating procedures for MAOs and have the intended effects on beneficiary protection and access to care.

That said, we recognize that not all MAOs are bad actors; many have active partnerships with providers in service of their shared patients and members and consistently act in good faith in trying to follow the rules. To this end, we believe that enforcement actions should be targeted, to the extent possible, to MAOs 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 MAOs who consistently act in good faith and adhere to CMS rules.

Data Collection and Reporting

There are limited data reporting mechanisms available to provide CMS with information about plan-level coverage denials, appeals and grievances, or delays in care resulting from plan administrative processes. These are important indicators of beneficiary access and are necessary for meaningful oversight of MAOs. For example, plans with excessively high rates of service and payment denials compared to other plans, or plans with unreasonably high rates of beneficiary grievances, may be indicative of inappropriate behavior that warrants further inquiry or audit. The 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.[6] We believe this could be a useful approach to conducting data-driven enforcement activity.

We recognize that CMS has proposed additional data and reporting requirements in a separate proposed rule specifically regarding prior authorization. The AHA will be submitting detailed comments in response to that related proposed rule, but in the context of MA oversight, we would like to underscore the importance of standardized, plan-level reporting and data collection for claim denials, appeals and grievances, in addition to the provisions included in the prior authorization proposal. We also believe it is important that CMS be the collector and aggregator of these reported data so they are presented accurately and completely in a standardized format that can be accessed in a single website. If such plan performance data is posted on individual health plan websites, instead of aggregated by CMS, it is unlikely to be used by CMS in a meaningful way to guide oversight and identify outliers in plan performance.

In addition, we recommend that existing MAO 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 MAO determination data in a relatively limited manner; the determination data are not used in Star Ratings and there is no documentation to suggest that this specific data drives oversight decisions like identifying which MAOs to audit. CMS could consider using existing data to identify MAOs for program audits to determine if the plan is correctly applying plan terms or medical necessity criteria; increase the frequency of plan-reported data to quarterly; publish a public list of MAOs that are subject to a Corrective Action Required (CAR) plan; or consider incorporating organizational determination data into Star Ratings. We included detailed recommendations on opportunities to enhance data collection and reporting in AHA's August 2022 RFI response.

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[6] Ibid.

Routine Auditing

CMS conducts routine audits for some aspects of the MA program, such as for the purpose of risk adjustment data validation. We believe that additional auditing is necessary to ensure compliance with CMS rules, especially those around medical necessity criteria, which are needed to achieve the intended alignment between Traditional Medicare and MA. Such audits should be focused on MAOs who are outliers in reported plan performance data or have a history of suspected or actual violations of CMS rules on their record. With these factors in mind, **we recommend that CMS regularly audit a sample of MAO denials, using a similar methodology as the 2022 HHS-OIG report, to review MAO determinations for the appropriate application of Medicare coverage rules and criteria**. Without this level of detailed auditing, there will be ample opportunity for certain MAOs 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 MAOs as users and providers of health care services and are therefore well-positioned to identify suspected violations of CMS rules that warrant further investigation. In fact, hospitals and health systems often act on behalf of their patients when working with insurers to obtain approval and coverage for medically necessary care, making them especially capable of identifying faulty or outdated program rules or bad actors. Unfortunately, there currently is no streamlined or direct way for providers to report such concerns to CMS. When issues are raised, they are frequently labeled as “contractual disputes” and therefore not subject to agency intervention. However, what may appear to be a contractual dispute actually may be evidence of a violation of federal policy, including systemic issues with the potential for negatively affecting patient care. Without a way for providers to report issues, CMS has no ability to establish a fact pattern needed to engage in enforcement activity. **Accordingly, we encourage CMS to establish a process for health care providers to submit complaints to CMS for suspected violation of federal rules as part of its enforcement strategy.**

Enforcement Penalties

Penalties are a necessary part of enforcement to ensure there is accountability for complying with CMS rules. Given CMS’ acknowledgement in the proposed rule that many of the included provisions are restatements of existing CMS policy, enforcement is critical to ensure meaningful change. We recommend that based on the results of audits and plan-reported data, CMS be prepared to initiate issuing warning letters and CARs to non-compliant MAOs. If the non-compliance persists, **we recommend that CMS impose intermediate sanctions (e.g., suspension of marketing and enrollment activities), civil monetary penalties (CMP) or terminate the contract.** To date, the non-interference clause has limited CMS involvement in many aspects of MAO compliance that are broadly considered contractual issues. However, we increasingly

believe this approach has allowed certain MAOs to circumvent CMS rules without accountability on issues that are not, in fact, contractual in nature, but directly and detrimentally affect patient care and access. As a result, we encourage CMS to take a more active role, where statutory authority permits, to investigate and sanction MAOs where appropriate for consistent violations of CMS rules, especially those discussed in this proposed rule which have a history of being consistently violated.

OVERPAYMENT PROVISION: HHS SHOULD NOT CHANGE ITS STANDARD FOR WHEN AN OVERPAYMENT IS "IDENTIFIED"

The proposed rule proposes to change its standard for an "identified" overpayment under 42 U.S.C. § 1320a-7k(d)(2)(A) to the "knowing" and "knowingly" standard in the False Claims Act. In so doing, the proposed rule relies on a single federal district court decision, *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 191 (D.D.C. 2018), *rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co. v. Becerra*, 16 F.4th 867 (D.C. Cir. 2021), *cert. denied*, 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21-1140). It explains that *UnitedHealthcare Ins.* found that a "knowing" and "knowingly" standard "would be consistent with" both the False Claims Act and the Affordable Care Act (ACA), and so the proposed rule appears to adopt that conclusion without independent analysis.

In reality, *UnitedHealthcare Ins.* did *not* offer any definitive holdings regarding the statutory term "identified." More importantly, the statute itself *does not* require HHS to interpret Section 1320a-7k(d)(2)(A) as requiring hospitals and health systems to return overpayments within 60 days of when the mere "existence" of an overpayment is known. Quite the opposite: The text and history of the ACA indicates that Congress intended that the word "identified" to have a different meaning than "knowing" or "knowingly." **Accordingly, HHS should <u>not</u> impose an unrealistically strict 60-day deadline on hospitals and health systems to return overpayments once they are on notice of an overpayment. Instead, once hospital and health systems know of the existence of an overpayment, HHS should allow a reasonable timeframe for them to identify exactly how much they must repay before any 60-day clock begins ticking.**

Contrary to the suggestion in the proposed rule, *UnitedHealthcare Ins. Co.* did not definitively interpret the term "identified." Instead, that decision merely held that the 2014 Overpayment's understanding of "identified" was not a logical outgrowth of the agency's proposed regulations and was thus imposed "without adequate notice." *UnitedHealthcare Ins. Co.*, 330 F. Supp. 3d at 192. If anything, *UnitedHealthcare Ins. Co.* held that there is no clear definition of the term "identified." Specifically, it explained that the ACA "did not define at what point [an overpaid entity] might be said to have 'identified' an overpayment, thus triggering the 60-day clock." *Id*. at 181. As such, any implication that one district court's reading of the state in *UnitedHealthcare Ins. Co.* requires HHS to amend its standard for when an overpayment is "identified" is incorrect.

The better reading of the statute is that the term "identified" has a *different* meaning than "knowing" and "knowingly." Starting with the plain text, the language on which the proposed rule relies provides that "[i]n *this subsection* … [t]he terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of title 31, United States Code." 42 U.S.C. § 1320a-7k(d)(2)(A) (emphasis added). But the relevant statutory term in the relevant subsection is "identified" — *not* "knowing" or "knowingly." (In fact, the terms "knowing" and "knowingly" appear *nowhere* in the subsection, which is likely the consequence of the statute's legislative history. *See infra* at 19 & n. 7.) Thus, the statute's adoption of any extrinsic definition of "knowing" or "knowingly" applies to *those* words. It does not apply to the word "identified."

What's more, under "ordinary principles of statutory construction[,] … where Congress includes particular language in one section of a statute but omits it in another section of the same Act, we generally take the choice to be deliberate." *Badgerow v. Walters*, 142 S.Ct. 1310, 1317-1318 (2022) (internal quotation marks omitted). Here, Congress chose to use a different word "identified" in the same subsection as where it defined the terms "knowing" and "knowingly." HHS therefore must conclude that Congress did so intentionally. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("We refrain from concluding here that the differing language in the two subsections has the same meaning in each. We would not presume to ascribe this difference to a simple mistake in draftsmanship"; *see also Allison Engine Co. v. U.S. ex rel. Sanders,* 553 U.S. 662, 671 (2008) ("The inclusion of an express presentment requirement in subsection (a)(1), combined with the absence of anything similar in subsection (a)(2), suggests that Congress did not intend to include a presentment requirement in subsection (a)(2)."). Put simply, then, the agency should read the term "identified" has having a *different* meaning than "knowing" and "knowingly" — exactly the opposite approach than it takes in this proposed rule.

To be sure, HHS has previously rejected this straightforward textual analysis. In the 2016 rule, it stated, "While we acknowledge that the terms 'knowing'' and ''knowingly' are defined but not otherwise used in section 1128J(d) of the Act, we believe that the Congress intended for section 1128J(d) of the Act to apply broadly." Medicare Program; Reporting and Returning of Overpayments, in Medicare Parts A and B, 81 Fed. Reg. 7654, 7660 (Feb. 12, 2016) (hereinafter "2016 Rule"). But this position flies in the face of fundamental principles of statutory interpretation. The Supreme Court has repeatedly emphasized that "the text of a law controls over purported legislative intentions unmoored from any statutory text. The Court may not 'replace the actual text with speculation as to Congress' intent.'" *Oklahoma v. Castro-Huerta*, 142 S.Ct. 2486, 2497 (2022) (quoting *Magwood v. Patterson*, 561 U.S. 320, 334 (2010). Here, the text is clear: Section § 1320a-7k(d)(2)(A) defines the terms "knowing" and "knowingly," but it does not define the term "identified." The agency's speculation about Congress' intent cannot override the words Congress actually chose to express that intent. HHS thus cannot offer the same interpretation, based on its own textual understanding of congressional intent, in this rulemaking.

If all of this were not enough, the ACA's legislative history supports this conclusion. The initial bill introduced by the House of Representatives in 2009 included a provision that was similar to the "report and return" provision ultimately enacted in the ACA, but which stated that "known," rather than "identified," overpayments had to be reported and returned within 60 days. *See* H.R. 3200, 111th Cong. § 1641 (as introduced by the House, July 14, 2009). But that was *not* the bill that Congress ultimately enacted. Instead, Congress adopted the *Senate's* version of the bill, which included the current 60-day deadline, using the word "identified" instead of "known." *See* Public L. 111–148 § 6402(a) enacting H.R. 3590, 111th Cong.[7] This change matters. "Few principles of statutory construction are more compelling than the proposition that Congress does not intend *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *I.N.S. v. Cardoza–Fonseca*, 480 U.S. 421, 442–43, 107 S.Ct. 1207, 94 L.Ed.2d 434 (1987). Here, both the text and history of Section 1320a-7k(d)(2)(A) clearly point in the same direction: The term "identified" must be read *differently* than "knowing" or "knowingly."[8]

There is a strong policy rationale for this approach. A 60-day timeframe for returning known overpayments is entirely unrealistic. Once a hospital or health system is on notice of the existence of an overpayment, it must conduct extensive and rigorous audits to identify exactly how much money must be returned. This requires identifying every claim that may have been overpaid by claim number, dates of service, and amount billed and paid. It also may involve complex statistical sampling followed by quality checks, as well as consultations with the Medicare Administrative Contractor. Given the six-year lookback period, moreover, in many instances claims data is already archived or stored on legacy systems and must be "restored" so that it can be queried for the unique claims at hand. And in some cases, identifying refunds involves applying different legal standards to different years of claims because Medicare rules change over time, complicating the analysis and identification. For larger health systems, all of this may require analysis across a number of hospitals in the system; for smaller hospitals, they may not have the resources to complete this work in 60 days or less. Such a requirement would create unnecessary administrative burdens on the health

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[7] As previous commenters have indicated, this legislative history almost certainly explains why Section 1320a-7k(d)(2)(A) defines terms that are not found in the relevant subsection. *See* 2016 Rule at 7660 ("Commenters noted that these terms are not used elsewhere in section 1128J(d) of the Act except the definition section. Commenters attributed section 1128J(d)(4)(A) of the Act as a drafting error based on the House version of the Affordable Care Act, H.R. 3962, which used the term 'knows.'"). As noted above, HHS erroneously rejected this commonsense explanation in favor of its own understanding of Congress' intent. *See Lamie v. U.S. Trustee*, 540 U.S. 526, 542 (2004) ("If Congress enacted into law something different from what it intended, then it should amend the statute to conform it to its intent. 'It is beyond our province to rescue Congress from its drafting errors, and to provide for what we might think ... is the preferred result.'" (Quoting *United States v. Granderson*, 511 U.S. 39 (1994) (Kennedy, J., concurring)).

[8] Bizarrely, some courts have relied on the legislative history of *other* statutes when analyzing the history of Section 1320a-7k(d)(2)(A). For example, one district court placed greater emphasis on a Committee Report from the 2009 Fraud Enforcement and Recovery Act as compared to the ACA, even though it acknowledged that the ACA's legislative history "cannot be dismissed as insignificant." *Kane ex rel. U.S. v. Healthfirst, Inc*., 120 F.Supp3d 370, 387-388 (S.D.N.Y. 2015). Needless to say, the history of the actual statutory language at issue, *i.e*., the word "identified" in the ACA, should carry more weight than any ancillary statutes that might be incorporated into the ACA's text.

care workforce and divert critical resources needed for patient care and operations. Further, it is highly unrealistic — indeed, nearly impossible — for hospitals of all sizes to conduct this kind of review within a 60-day timeframe. It is fair to say that Congress could not have intended this approach. Yet the proposed rule's reading of Section 1320a-7k(d)(2)(A) would expose hospitals and health systems to False Claims Act liability (including statutory penalties, treble damages and potential debarment) if they do not return overpayments on this unworkable 60-day schedule.

To make matters worse, an unfeasibly short timeline runs the serious risk of creating "false positives," where what at first may appear to be an overpayment (or underpayment), really is not. As HHS knows, this problem frequently occurs, even under the current timeline. For example, one AHA member has reported that it is currently working with HHS to resolve two underpayments worth nearly $2 million due to lags or errors in pricing updates to the contract management software that providers use to calculate expected payment. In this case, there was a difference between actual and expected payment that the software had not yet captured. Reasonable time was needed to investigate whether it was an overpayment, an underpayment or a software error, and even still the agency needed to work with HHS to correct the "false positive." If the timeline becomes more compressed, this phenomenon will occur more frequently because hospitals will need to err on returning money they are actually owed, thereby creating administrative burdens for providers and CMS.

The agency is well aware of these practical realities. The 2016 rule correctly determined that "completing these investigations may require the devotion of resources and time," and that "[r]eceiving overpayments from Medicare is sufficiently important that providers and suppliers should devote appropriate attention to resolving these matters." 2016 Rule at 7662; *see id*. at 7663-7664 ("We expect providers and suppliers … to quantify, report, and return the entire overpayment in good faith. . . Providers and suppliers are obligated to conduct audits that accurately quantify the overpayment. After finding a single overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim.") As such, that rule struck a balance by stating that a "total of 8 months (6 months for timely investigation and 2 months for reporting and returning) is a reasonable amount of time, absent extraordinary circumstances affecting the provider, supplier, or their community." *Id*.

Here, the final rule should define the term "identified" to account for these realities. **HHS should again afford overpayment recipients sufficient time to conduct audits and investigations to identify the size, scope and nature of overpayments, so long as that recipient demonstrates good faith while working to quantify the exact amount it must return to the Secretary.** *See* 2016 Rule at 7661 ("When a person obtains credible information concerning a potential overpayment, the person needs to undertake reasonable diligence to determine whether an overpayment has been received and to quantify the amount. The 60-day time period begins when either the reasonable diligence is completed or on the day the person received credible

information of a potential overpayment if the person failed to conduct reasonable diligence and the person in fact received an overpayment.") At a minimum, the final rule should restore that presumptive eight-month identification and return period; in fact, because certain identification processes take longer than eight months, it should extend that period or grant hospitals and health systems further leeway so long as good faith steps are being taken to identify and return overpayments. **The statutory term "identified" amply permits this approach, and nothing in the district court's opinion in *UnitedHealthcare Ins. Co.* forecloses it.**

At the same time, 60 days after a recipient has, in fact, identified the overpayment amounts it must return or 60 days after it has failed to demonstrate good faith in identifying the precise contours of return obligations, *only then* can it be deemed to have "knowingly" retained those funds in violation of the False Claims Act. *See* 42 U.S.C. § 1320a-7k(d)(3) ("Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of Title 31) for purposes of section 3729 of such title.") Again, this concept was properly captured in the 2016 rule. *See* 2016 Rule at 7660 ("The enforcement provision at section 1128J(d)(3) of the Act depends on the person retaining the overpayment after the deadline for reporting and returning."); *id*. at 7665 ("[O]ur discussion of the FCA is limited to its explicit inclusion in the enforcement provision under section 1128J(d) of the Act, which states that any overpayment retained by a person after the deadline for reporting and returning the overpayment under this rule is an obligation for purposes of the FCA."). Indeed, it is here — in the statute's *enforcement* provision — where False Claims Act principles are most appropriately located.

In the end, because the statute does not explicitly define the term "identified," because that term manifestly adopts a different standard than "knowing" or "knowingly," and because it is virtually impossible for hospitals to complete a careful, prudent and accurate accounting of overpayments in only 60 days, a more balanced approach to the 60-day clock is both legally permissible and sound policy. **HHS should adopt a definition of "identified" that does not impose impractical deadlines on hospitals and health systems before exposing them to False Claims Act liability. To that end, HHS should withdraw this portion of the proposed rule and/or restore the portions of the 2016 final rule that afford providers with the necessary time to investigate and accurately identify overpayments.**

CONSUMER PROTECTION AND MARKETING REQUIREMENTS

CMS has proposed a number of actions to curb marketing practices that may be potentially confusing or misleading to consumers shopping for Medicare coverage. We believe this is an important step forward for consumer protection and reflects the importance of seniors having access to accurate and complete information about their Medicare options to make informed coverage choices. Hospitals and health systems nationwide regularly encounter Medicare beneficiaries who do not understand their

coverage or benefits or who may have been enrolled in an MAO without fully appreciating their options or the potential implications of opting out of Traditional Medicare coverage. We also have heard from some members that they occasionally work with patients who report being unaware that their coverage was switched from Traditional Medicare to coverage through a private MAO and believe this was done without their consent.

Health care providers often play a critical role in providing financial counseling and other resources to support patients in understanding their coverage and benefits, but more should be done at earlier stages in the shopping and plan selection process to promote health literacy and informed plan selection. The consumer protections included in this section are an important starting place to ensure that current and prospective Medicare beneficiaries have accurate information about their Medicare options and are not subject to misleading or confusing information intended to sway their enrollment decisions.

We thank you for the opportunity to comment on these important topics. We particularly appreciate CMS' thoughtful proposals to improve how the Medicare program works for patients and their providers and appreciate your consideration of our recommendations. **We urge CMS to expeditiously finalize the health plan oversight and consumer protections included in the proposed rule and to adopt our recommended modifications to the proposed policy on overpayments**. Please contact me if you have any questions, or feel free to have a member of your team contact Michelle Kielty Millerick, AHA's senior associate director for health insurance and coverage policy, at mmillerick@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

Appendix A: Case Examples: How Inappropriate MAO Denials Affect Patient Care

APPENDIX A: Case Examples
How Inappropriate MAO Denials Affect Patient Care

Inpatient Admissions

- An AHA member shared the case of a 76-year-old woman who was suffering from vaginal bleeding and abdominal swelling. She was referred to a gynecologic oncology specialist for treatment given the complexity and severity of her condition. Upon diagnosing the patient with endometrial adenocarcinoma, a blood clot in her lung, ascites (abdominal fluid buildup), and severe sodium deficiency, the oncologist admitted the patient to the hospital for urgent treatment in order to immediately initiate a high toxicity regimen of chemotherapy with potent side effects. Over the following three days, the patient received complex chemotherapy treatment with anticoagulation therapies, surgical removal of excess abdominal fluid, steroids, and intravenous fluids, in addition to necessary labs and interventional radiology. Despite being critically ill, the patient responded well to initial treatments and was discharged in the afternoon of the third day to continue outpatient chemotherapy sessions and ongoing visits for supportive care and abdominal fluid drainage. Despite the care definitively meeting Medicare criteria and extending over more than two midnights (the standard for Traditional Medicare to cover the case as inpatient admission), the MAO denied the patient's inpatient stay and classified her care as "observation." This case continues to be adjudicated but is a common example of how certain MAOs are routinely adopting more restrictive—and inappropriate—coverage criteria for inpatient admissions and other critical health care services.

- An AHA member health system reported an 80-year-old patient suffering from pneumonia, dehydration, malnutrition and other comorbidities who was admitted to the hospital as an inpatient and received care for eight days. Despite exceeding both the CMS two-midnight rule (by multiple days) and MCG criteria, the patient's MAO downgraded her stay to observation. Under Traditional Medicare rules, this case would have been classified and paid as inpatient care, but frequently, MAOs will create their own (and more restrictive) criteria to justify downgrading the case to observation status. This practice allows plans to pay for care at a lower outpatient rate despite eight days of intensive inpatient level care being provided. Such classifications misrepresent the care received by the patient, may impede a patient's ability to receive coverage for certain benefits and care plans after discharge and require lengthy appeals processes that increase the cost of care delivery.

Other Medical Necessity Criteria Examples

- The story of Christopher McNaughton, a Penn State University student, whose United Healthcare plan denied coverage of his treatment for ulcerative colitis shows the devastating outcome of overly restrictive or inconsistently applied medical necessity criteria. Christopher's treatments amounted to over $2 million per year, resulting in his case being flagged by United as a "high dollar account" warranting a series of repeated medical necessity reviews. United determined on several occasions that the treatment was not medically necessary, even after the first few months of treatment — which United initially approved — brought Christopher's debilitating condition under control for the first time. Christopher's story also highlights how critical medical necessity findings were misrepresented during the insurer's review process and warnings from both his doctor and at least one external medical reviewer about the risks of altering Christopher's treatment plan were ignored. While Christopher is not an MA enrollee, we believe many of the challenges described in his case regarding the application of overly restrictive or inconsistent medical necessity criteria reflect a common theme and are a pressing patient protection issue.

Mid-Year Contract Changes

- An AHA member hospital recently shared the experience of a cancer patient who had been receiving a course of chemotherapy treatment since 2019. In 2022, the patient's insurer adopted a mid-year site of service policy for certain specialty medications and denied coverage of her remaining six chemotherapy treatments at the hospital where she had received all previous infusions for the last three years. The patient's care was delayed while her provider scrambled to negotiate a partial exemption to the site of care policy through the end of the calendar year. Meanwhile, the insurer pushed for a single case agreement to get a discount on the care provided, despite the presence of a contract and at the expense of the patient's timely access to ongoing chemotherapy treatment. Unfortunately, these circumstances are not uncommon and underscore the need for the site of service protections included in the proposed rule to preserve patient access in the most appropriate setting.

Continuity of Care

- A provider treating a man with a deadly skin cancer (metastatic melanoma) requested imaging scans every three months to assess the progress of ongoing therapies. Unfortunately, the patient's health plan required a new prior authorization for each treatment, a process that frequently delayed the patient's care by weeks at a time, interrupting the timely administration of cancer therapies

and monitoring of disease progression. Patients deserve health coverage that does not interrupt potentially life-saving treatments that are inherently time sensitive, such as cancer treatment regimens.

Post-Acute Care

- An AHA member shared the experience of a 54-year-old patient with multiple recent hospital admissions who presented to an acute care hospital with infected pressure ulcers, urinary tract infection, acute kidney injury and pneumonia. After primary acute care interventions, the general acute care hospital referred the patient to a LTACH to execute a post-acute plan of care including wound care, pain and nutrition management, physical and occupational therapy, monitoring of labs including renal function, and daily medical management. The MAO denied the LTACH placement three times in a single month, indicating each time that the patient did not meet medical necessity criteria for an LTACH stay and recommended a lower level of care. After three denials without a successful appeal, the MAO forced the patient to be discharged to a SNF, against the recommendation of the patient's physician and care team. The patient's condition significantly worsened during this time and the patient was readmitted to the general acute care hospital within a month. After subsequent treatment, a fourth attempt to receive MAO authorization to transfer the patient to an LTACH for appropriate PAC services required a peer-to-peer review before being ultimately approved — *more than two months after it was first requested*. This represents a two-month delay in medically necessary care for an acutely ill patient whose opportunity for a full and speedy recovery was compromised as a result of inappropriate plan denials.

- One of the HHS-OIG report examples (Case D278) recounted the experience of a 68-year-old patient with chronic obstructive pulmonary disease, congestive heart failure and peripheral vascular disease, whose referral to an IRF was denied by the MAO. The beneficiary was admitted to the hospital with a femur fracture and underwent a screw placement surgery. After the surgery, the beneficiary developed anemia and pneumonia. The MAO denied the request stating that the beneficiary's condition did not meet all medical necessity criteria for admission to an IRF under Medicare guidelines. *The MAO recommended instead that the beneficiary could be discharged to a SNF, HHA or home with outpatient therapy*. The HHS-OIG physician panel determined that the recommendations for outpatient therapy were not sufficient and that admission to an IRF was necessary and consistent with the Medicare Benefit Policy Manual. The beneficiary had ongoing medical conditions that could generate more medical complications if not closely assessed by a physician daily. The beneficiary also had the ability and need to participate in physical therapy and

occupational therapy for three hours at least five days per week, needed help with walking, and at least two people to help with balance and recovery from the screw placement in the beneficiary's hip. At the time of the HHS-OIG report publication, this decision had not been reversed.

Emergency Services

- In one example of inappropriate downcoding, an AHA member hospital shared the experience of a 15-year-old patient who presented to the emergency department with an attempted overdose.[9] It was determined that the overdose was intentional, and she was diagnosed with suicidal ideations, major depressive disorder, mood disorder and personal history of self-harm. The hospital billed CPT code 99285, which is for a level 5 emergency department visit to address "problem(s) [that] are of high severity and pose an immediate significant threat to life or physiologic function."[10] A psychiatric case involving an intentional attempted overdose reasonably meets this definition. However, the health plan downcoded this case to a lower-level visit despite the diagnosis codes on the claim clearly supporting the billing of a level 5 emergency visit. In fact, the insurer's policy manual lists "suicidal or homicidal patient" as a clinical example of when CPT code 99285 would be appropriately used.

White Bagging

- One AHA health system member shared the experience of a cancer patient whose health plan implemented a white bagging policy for the patient's specific treatment needs. In this instance, the mandated white bagging policy resulted in a care delay of more than a month due to shipping delays from the third-party specialty pharmacy. The first medication shipment had to be discarded upon arrival because it was improperly stored overnight on a freight truck, making it no longer safe to use for treatment given the inappropriate storage conditions for a medication requiring specific temperature controls. Since the initial shipment was unusable, the medication was reordered and the patient was rescheduled for the infusion a few weeks later. The day before the rescheduled appointment, the health system pharmacy was notified that the medication delivery would be delayed due to inclement weather across the country, requiring the patient's appointment to be rescheduled a second time. After a month-long delay directly attributable to white bagging processes, the care team was concerned about

[9] This example, provided by a member hospital, occurred with a commercial insurer that has a large footprint in the MA market. While this specific example is from a commercial insurance product, the issue of emergency department downcoding is broadly applicable in MA products, where MAOs commonly apply the same set of problematic policies and utilization management tools that are used in the commercial insurance market.
[10] MAO Policy Manual, CPT 99285/HCPCS G0384 High Complexity

potential clinical ramifications of the delayed care and sought a waiver of the white bagging policy for this patient. The health plan eventually agreed to provide a waiver for one dose only, allowing the health system pharmacy to intervene before even greater patient harm occurred. However, the health plan required the provider to revert back to the white bagging process for future doses. The health system had the necessary medication in stock throughout the duration of these delays and, without an insurer-mandated white bagging policy, could have provided it to the patient as intended from the outset. Instead, the white bagging requirement forced the patient to go without medically necessary care for over a month while the hospital tried to negotiate on their behalf to resolve the situation.

- The story of Landon Claeys, a child with cerebral palsy, who requires Botox injections to help loosen his muscles shows how his treatment was delayed by more than a month due to insurer white bagging requirements.[11]

Appeals

- A large, national MAO has a policy of responding to appeals within 60 days of a provider filing an appeal post-denial. The MAO has a significant backlog of appeals and has acknowledged they are behind in their review and not able to meet the expected timeline. An AHA member health system currently has 140 outstanding appeals with this MAO alone – all for MA beneficiaries – that are greater than 60 days where they have not yet received a response from the MAO. Of the 140 outstanding appeals, nearly 50% are from the first half of 2022, far exceeding the 60 day timeline for responding. This unnecessarily delays adjudication of the claim for the patient and their provider while unfairly creating barriers to timely resolution of appeals, which can impact patient access to care. Notably, providers must adhere to strict timeline requirements for submitting claims and appeals or risk foregoing payment or reconsideration, but certain MAOs violate their own policies with limited external accountability for being unable to review or respond to appeal requests for nearly a year.

Peer-to-Peer Requests

- An AHA member recently reported that they had trouble getting in touch with an MAO after a denial. After a significant delay, the MAO responded with a request for a peer-to-peer review and indicated the provider needed to secure a physician to conduct the peer-to-peer *within the next 10 minutes* or the case would be denied. Such practices circumvent the intent of peer-to-peer conversations — to allow clinicians to discuss the merits of a patient case and

[11] https://www.wha.org/Patients-First-Wisconsin/Stories/Stories/Patient-Story

the pros and cons of an approach and allow MAOs to deny patient care for administrative reasons unrelated to patient need or clinical merit.