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February 13, 2023

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 over 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) 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.

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small critical access hospitals, mid, and large-sized hospitals, and academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

OVERVIEW

Over the past few years, as our members have faced unprecedented challenges in meeting the care needs of people in our communities, our members also unfortunately experienced growing challenges in working with Medicare Advantage Organizations (MAOs) to secure timely authorization and payment for care provided to patients, often resulting in unnecessary care delays and increased administrative burdens.

While utilization management programs have a purpose in preventing fraud and abuse, our members have experienced a growing trend in what can only be characterized as a misuse of utilization management programs, impeding the critical doctor-patient relationship and resulting in care delays and unnecessary waste in the health care system. In the Medicare Advantage program, this misuse includes inappropriate denials 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. All these not only add to administrative burden on an already overtaxed workforce, but importantly can have a negative impact Medicare patients.

The proposed rule includes important protections for MA beneficiaries and clarifications for MAOs that, *if monitored and enforced*, will improve how coverage works for enrollees, promote more timely access to care, strengthen access to behavioral health providers, help patients understand their Medicare coverage options, and reduce the administrative burden of health plan requirements on health care providers.

We strongly support the proposed changes intended to strengthen consumer protections and oversight of MAOs, which are critical and urgently needed, and we encourage CMS to implement processes for monitoring and enforcement of these provisions.

The proposed rule also makes changes to the legal standard for identifying overpayments, greatly reducing the time available for providers to investigate and appropriately return overpayments.

Therefore, we also offer our concerns about the proposed changes to the legal standard for identifying overpayments and recommend that CMS either withdraw this section of the proposed rule or restore the portions of prior CMS rulemaking on overpayments which afforded providers with the necessary time to investigate and accurately identify overpayments.

PRIOR AUTHORIZATION AND MEDICAL NECESSITY

As reinforced in the proposed rule, 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. However, as the recent OIG report¹ confirmed, and as our members have experienced, that aim is not consistently achieved. ***In order to achieve an equivalent level of service and access, we strongly support CMS' proposal to limit MAOs from adopting more restrictive rules than Traditional Medicare.***

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 when determining medical necessity would be significantly beneficial for patients.

Despite existing CMS rules precluding MAOs from using clinical criteria that are more restrictive than Traditional Medicare, our members routinely experience MAOs doing exactly that. Currently, MAOs often classify their medical necessity criteria as proprietary, resulting in a “black box” when hospital staff attempt to determine whether a service will be approved. This lack of transparency is a frequent reason that prior authorization and claim reimbursements are delayed or denied.

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 retrospectively downgraded to observation stays, even in situations where the clinical necessity for the admission far exceeds plan requirements. For example, one of our hospitals recently reported that one MAO has begun denying nearly all inpatient admissions, including those where patients are hospitalized for multiple days. They also report that scheduled peer-to-peer consultations are often canceled by the MAO, rescheduled and canceled again by the MAO and this happens multiple times.

¹ <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

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 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 hospital stays that exceed two midnights to observation status. ***While we appreciate this as the intent of the proposed rule, to enhance clarity and adherence, we also encourage CMS to offer greater specificity and delineate the specific rules that MAOs must follow pursuant to Traditional Medicare coverage rules where possible. For example, we urge CMS to explicitly state that MAOs must follow the Two-Midnight rule, as opposed to leaving this to the MAOs' interpretation.***

Relevant Medical Expertise to Review Medical Necessity Determinations

WHA supports CMS's proposed update to § 422.566(d), which seeks to ensure appropriate personnel make medical necessity determinations for MA beneficiaries. Our members' patients should be able to rely on the expert judgment of their medical care team as opposed to a health plan clinician who has never treated or even met the patient — and may not have the same training or specialty expertise as the treating physician. To ensure that denials are made based on relevant and applicable medical expertise, the MAO's reviewing clinicians must have appropriate training in the field of medicine for the service being requested.

One area in which this is particularly important is peer-to-peer discussions. Our physicians frequently participate in MAO-required peer-to-peer discussions as part of the health plan appeals process where our clinicians explain the merits of their recommended treatment approach and advocate for its coverage. Our specialists often report that they encounter MAO medical professionals who do not have applicable expertise in the requested service discipline yet are responsible for conducting medical necessity reviews in that service area.

We appreciate CMS's recognition of this issue in proposing updates to the qualifications of the reviewing clinician. ***We urge CMS to specify that these rules apply to peer-to-peer discussions in addition to prior authorization reviews. We also recommend CMS clarify that this provision applies to expedited reviews in addition to standard requests for prior authorization.***

Also, as noted earlier, our members often experience multiple cancellations of scheduled and reschedule peer-to-peer consultations for a single case. Thus, we encourage CMS to also consider appropriate guardrails to ensure MAOs respond timely to peer-to-peer requests.

Site of Care Protections

WHA supports the proposed rule's provisions designed to protect patients from unnecessary site of care 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, as 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 in effect 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.

We recommend that CMS 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 many, particularly vulnerable patients. As a result, ***we support these important patient protections to support continuity of care.***

IMPROVING BEHAVIORAL HEALTH ACCESS

WHA supports CMS proposals to expand access to behavioral health services and strengthen MAO provider networks. Inadequate behavioral health provider networks have been a consistent problem for many years, impeding access to critical services. As a result, hospitals and health systems face very real challenges in supporting patients experiencing behavioral health crises who often spend extended periods of time in inappropriate settings (like the emergency department) waiting for an available bed or for MAO authorization to be transferred to another setting.

We also support CMS's proposal to add clinical psychologists, licensed clinical social workers and prescribers of medication for opioid use disorder 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. 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.

IMPROVING ACCESS TO POST-ACUTE CARE SERVICES

WHA supports the steps CMS has taken in this proposed rule to address concerns regarding MA beneficiary access to medically necessary post-acute care (PAC) services. Institutional PAC providers, including inpatient rehabilitation hospitals and units (IRFs), long-term care 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.

However, MA beneficiaries are frequently denied access to these covered services or suffer long delays in receiving authorization for transfer to an appropriate PAC facility. This harms patients who are robbed of specialized rehabilitation care to optimize their chances of recovery, exacerbates capacity issues at

general acute care hospitals and saddles health care workers with time consuming administrative appeals processes to get patients what they need.

Accordingly, CMS' proposed 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. In addition, to shore up the protections proposed in this rule and to ensure the availability of appropriate PAC services in MAO networks, ***we recommend that CMS add a requirement that IRFs, LTCHs and HHAs be explicitly added to MA network adequacy requirements.***

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 implement important guardrails needed to 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.

Many of the policies in the proposed rule 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, and pathways for stakeholders including health care providers to report suspected violations and penalties for non-compliance. ***We encourage CMS to implement oversight processes as these 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.***

CHANGES TO THE STANDARD FOR IDENTIFYING OVERPAYMENTS

CMS' proposal to change the legal standard for identifying an overpayment (from the current standard of "reasonable diligence" to the False Claims Act definition of "knowingly") would result in an unrealistic strict 60-day timeline to return overpayments once they have been identified. This new proposed timeline will be nearly impossible to meet, subjecting organizations to unnecessary False Claims Act liability even when we are acting in good faith to comply.

Although it is unclear exactly why CMS believes it is necessary to change its approach, the proposed rule incorrectly suggests that it is legally required to do so. The text and history of the relevant statutory provision (42 U.S.C. § 1320a-7k(d)(2)(A)) indicate that CMS must afford overpayment recipients with sufficient time to conduct audits and investigations to identify the size, scope and nature of overpayments, so long as that overpayment recipient demonstrates good faith while working to identify the exact amount it must return to the Secretary.

There was good reason for Congress to adopt this approach. A 60-day timeframe for returning overpayments, without an appropriate period to investigate and quantify the overpayment, is entirely unrealistic. Once we identify a potential overpayment, our compliance and revenue cycle teams conduct an extensive and rigorous audit investigation to collect facts, identify the source of the discrepancy, mitigate any continuing circumstances if the issue is ongoing, and determine 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” such 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, further complicating the analysis and identification.

Previous CMS rulemaking on this topic, including the 2016 Final Rule on Reporting and Returning Overpayments, appropriately recognized these practical realities and clarified that up to six months is permitted to conduct a necessary investigation and appropriately quantify an overpayment. HHS should not deviate from this current practice and impose an unrealistically strict 60-day deadline on hospitals and health systems to return overpayments. Instead, once we 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 is triggered. No judicial decision —and certainly no statute — requires any change in CMS’s existing approach. ***To that end, we oppose this change in the proposed rule and ask HHS to 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.***

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We appreciate CMS’s thoughtful proposals to improve how the Medicare program works for patients and their providers and appreciate your consideration. If you have any questions, please feel free to contact Joanne Alig, WHA’s Senior Vice President for Public Policy, at jalig@wha.org.

Sincerely,



Eric Borgerding
President & CEO