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February 13, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
Baltimore, MD 21244-8013
Submitted electronically via https://www.regulations.gov

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A,B,C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure:

On behalf of our more than 450 member hospitals and health systems, the Texas Hospital Association (THA) appreciates the opportunity to provide comments on the above-referenced proposed rules, specifically the policy and technical changes to the Medicare Advantage Program (MA). With 47% of Medicare beneficiaries in Texas now enrolled in MA plans, including 50-80% in markets such as Houston, El Paso, and Fort Worth,[1] Texas hospitals are eager to work with CMS to ensure MA serves beneficiaries consistently with the standards of the traditional Medicare program. These comments address CMS' proposals regarding the following issues:

1. Medication Therapy Management (MTM) Program (§ 423.153);
2. Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112,422.137, 422.138 and 422.202);
3. Medicare Advantage (MA) and Part D Marketing (Subpart V of Parts 422 and 423);
4. Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116); and
5. Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act (§§ 401.305(a)(2), 422.326(c), and 423.360(c)).

[1] The Commonwealth Fund. (2022). Medicare data hub: Medicare advantage. Available at: https://www.commonwealthfund.org/medicare-data-hub/medicare-advantage

1. **Medication Therapy Management**

Recommendation: THA **supports** CMS' proposal to revise the MTM targeting criteria to promote consistent, equitable, and expanded access to MTM services.

Background

Hospitals incur higher costs in treating patients with one or more chronic conditions, including diabetes, hypertension, dyslipidemia, chronic congestive heart failure, Alzheimer's, end stage renal disease, asthma, chronic obstructive pulmonary disease, bone-disease arthritis, mental health conditions and HIV/AIDS.[2] Within the last three years, patient acuity has increased as measured by average length of stay in part due to patients with chronic diseases delaying care during the pandemic.[3] THA supports CMS' proposal to revise the MTM targeting criteria by requiring all Medicare Part D (Part D) plan sponsors to target beneficiaries suffering from these diseases by specifically naming them in the regulation and adding HIV/AIDS, lowering the maximum of drug requirement to 5 from 8, and lowering the cost threshold to the average annual cost of 5 generic drugs. One Texas hospital noted that these proposals will improve access to routine and critical medications for their Part D patients suffering from the aforementioned diseases and will reduce their costs in treating these patients.

2. **Improvements to MAO Utilization Management Requirements & Prior Authorization Processes**

Recommendation: THA **strongly supports** CMS' proposals to improve the utilization management requirements imposed by Medicare Advantage Organizations (MAOs). We urge CMS to hold MAOs accountable to these strengthened requirements and offer recommendations for meaningful enforcement as the agency moves to implement them.

Background

In April 2022, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a report documenting "widespread and persistent problems related to inappropriate denials of services and payment" across MA plans industry-wide.[4] The report's findings closely resemble the experiences of THA member hospitals with MA plans, as they absorb a relatively higher share of MA patients each year relative to traditional Medicare. The OIG report confirms THA member hospitals' experiences that inappropriate prior authorization denials are occurring both *before* care is delivered, interrupting medically necessary care for MA beneficiaries, and *after* care is delivered, denying payment and encumbering patients with unexpected financial

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[2] American Hospital Association. (2021). 2021 Cost of caring report. Available at: https://www.aha.org/guidesreports/2021-10-25-2021-cost-caring

[3] American Hospital Association. (2022). Massive growth in expenses and rising inflation fuel continued financial challenges for America's hospitals and health systems. Available at https://www.aha.org/system/files/media/file/2022/04/2022-Hospital-Expenses-Increase-Report-Final-Final.pdf

[4] U.S. Department of Health and Human Services Office of Inspector General. (2022 April). Some Medicare Advantage Organization denials of prior authorization requests raise concerns about beneficiary access to medically necessary care. Available at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

obligations. 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 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.[5] **As a result, THA strongly supports 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 MAOs 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 — which today are often inconsistent with Medicare coverage rules — would be significantly beneficial for MA patients.

Despite existing CMS rules precluding MAOs from using clinical criteria that are more restrictive than Traditional Medicare, we routinely experience MAOs doing exactly that. Currently, MAOs often classify their medical necessity criteria as proprietary, do not share specifics with hospitals, and modify their criteria without warning. When an MAO's medical necessity criteria are not known, hospitals are left to try to reconstruct what each MAO's criteria might be based on patterns of approval and denial. As one Texas hospital CEO comments, "as soon as you get your process somewhat in order, [the MAOs] move the goalposts on you and you don't know how to fix it because they won't tell you." This lack of transparency is a frequent reason that prior authorization and claim reimbursements are delayed or denied.

Hospital inpatient admission and post-acute transfer are areas 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 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. One Texas hospital who accepts CMS' Medicare Managed Care Manual as its clinical criteria for admission noted that MAOs refuse to acknowledge present-on-admission conditions common to the industry that meet clinical guidelines and warrant inpatient admission. As a result, MAOs refuse to approve the patient's inpatient status which increases the hospital's costs (e.g. having hospital physicians and/or other clinicians spend time and effort to defend appropriate bed status to the MAO). Ultimately, the MAO refuses to pay the hospital its legitimate reimbursement – due wholly to the MAO denying and disagreeing with the clinical criteria for admission.

Other Texas hospitals have noted that MAOs typically require prior authorization before a hospital can transfer a patient to a post-acute facility or home health, and often delay their prior authorization decision for days. This hospital noted that the delays create chokepoints of access to the hospital since the patient cannot be discharged and occupies a hospital bed that is needed

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

for another acute patient. The MAO has a perverse incentive for to avoid approving a transfer to the next site of care when acute care is reimbursed at a flat rate and the inpatient amount is exhausted, as the transfer would require a separate reimbursement but prolonging their stay in acute care would not. Lengths of stay increase, burdening the patient by keeping them hospitalized longer than needed and increasing risk of hospital-acquired infection, while the hospital absorbs the costs of housing a patient no longer meeting criteria for acute inpatient admission. This entire chain of events takes place due to prior authorization and reimbursement delays that have become characteristic of MAOs. Refusing timely reimbursement drives up costs across the entire health care system, as the hospital must recover unreimbursed expenses elsewhere.

Misapplication of proprietary medical necessity criteria directly jeopardizes lifesaving care, as illustrated in another example given by a different Texas hospital. At this rural hospital, a patient over age 90 on blood thinners presented after falling and hitting their head. The MA plan denied authorization for a CT scan to check for a suspected brain bleed, stating it was not medically necessary. According to this hospital, CT scans in such circumstances are routinely approved as medically necessary for traditional Medicare patients, whereas MAOs deny such services when a more basic imaging procedure or conservative treatment was not first tried. Due to the patient's condition, the hospital performed the CT scan anyway, confirming a brain bleed requiring transfer to a higher level of care. That night, the patient was flown to another facility and received treatment that saved their life. If the local hospital had abided by the CT scan denial from the MA plan, this patient would not have survived. This story is consistent with findings from the OIG report that advanced imaging services were the most common source of inappropriate MA denials.

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. Inappropriate denials of medically necessary advanced imaging and other services would also be reduced under CMS' proposal, which prohibits clinical criteria that restrict access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD. **THA urges 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 coverage rules. One Texas hospital described the proposals in §422.101 as "some of the most powerful changes CMS can make."**

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, THA also recommends **that CMS adopt more specific language regarding the Traditional Medicare rules that MAOs are required to follow.** For example, 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. **THA urges CMS to explicitly state that MAOs must follow the Two-Midnight rule, for example, as opposed to leaving this to an interpretation of logic**. Two precise clarifications we request include: (1) that the same rules regarding the start of care for determining the Two Midnight Benchmark apply, including receipt of care directed at the patient's presenting symptoms, as well as time spent at another Medicare participating ED or hospital; and (2) that the Two Midnight Presumption apply to Medicare Advantage enrollees – that absent evidence of abuse or gaming, that inpatient hospital stays of two midnights or more after formal admission not be the focus of inpatient utilization review.

Relevant Medical Expertise to Review Medical Necessity Determinations

THA commends CMS's proposed update to § 422.566(d), which seeks to ensure appropriate personnel make medical necessity determinations for MA beneficiaries. Our 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, 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 can 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. **Accordingly, we appreciate CMS's 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. We also recommend CMS clarify that this provision applies to expedited reviews in addition to standard requests for prior authorization.**

We also recommend CMS take the additional step of clarifying payor physicians in peer-to-peer consultations may not deny a service without considering all facts related to the patient in question. According to some Texas hospitals, payor physicians uniformly issue or uphold denials based on indications from first-line screening tools for admission criteria (e.g., InterQual, Milliman), disregarding other facts influencing a physician's medical judgement that the patient has non-routine clinical needs. We recommend that CMS clarify its expectation that MAO physicians use screening tools and routine criteria for admission as decision support tools, but not as a substitute for the judgement of a physician who has personally treated the patient and offered facts that support a different course of treatment.

Site of Care Protections

THA commends CMS for the inclusion of 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

THA strongly supports and recommends 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. One Texas hospital noted that CMS' proposal requiring a prior authorization be in place for at least 90 days would decrease the number of coverage gaps for patients that switch plans during treatment. As a result, **we commend CMS for codifying these important patient protections to support continuity of care, and stress the importance of finalizing these proposals.**

Enforcement and Oversight

Texas hospitals frequently stress the need for meaningful enforcement of penalties for plans who consistently fail to authorize medically necessary care. In this rule, CMS has thoughtfully addressed a wide range of stakeholder concerns about MAO policies and practices which may delay or restrict access to care. 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. However, the rule is light on specifics with regard to the agency's intended enforcement protocol.

As CMS moves to implement these improvements, we offer the following recommendations for measures CMS could consider to hold plans accountable and ensure compliance.

A. Standardize the complaint process for hospitals and other providers with grievances regarding the prior authorization practices of MA plans. CMS should have transparency into complaints, actively monitor complaints industry-wide, and formalize a role for the agency to intervene in complaints that are repeated, severe, or taking excessive time to resolve. One immediate option to achieve this would be to allow providers to appeal to the Qualified Independent Contractor and Administrative Law Judge for the MAOs, as they can with traditional Medicare. This would support the agency's aim of consistency between Medicare Advantage and traditional Medicare and will give CMS better insight into problematic MAO practices.
B. Develop and enforce a tiered penalty structure for MA plans who consistently fail to authorize medically necessary care for beneficiaries. First-line actions may include written notices and corrective action plans, escalating through financial and administrative penalties up to and including termination of a MA organizational contract.

3. Improving Beneficiary Protections with Respect to MA and Part D Marketing

Recommendation: THA ***strongly supports*** CMS' proposals to oversee Medicare Advantage and Part D Marketing revisions.

THA commends CMS for its proposals to strength beneficiary protections against predatory or misleading marketing practices that have been present with respect to MA and Part D. Specifically, THA supports CMS' proposals to require sales agents to explain the effect of a beneficiary's enrollment choice on their current coverage whenever the beneficiary makes an enrollment decision. Aggressive and deceptive marketing campaigns create confusion among older adults. Many Medicare beneficiaries unknowingly sign up for a MA plan. Some do not realize they are switching from traditional Medicare to an MA plan until they seek care. Others inadvertently choose MA instead of supplemental coverage. To protect patients and ensure clarity, one Texas hospital created education materials to help patients understand the potential implications of opting into MA, such as limited choice of providers, limited access to care, and hidden costs.

THA also applauds CMS' proposal to require MAOs and Part D sponsors to oversee and monitor their agent/broker activities and report agent/broker non-compliance to CMS. The requirements that would provide more oversight of third-party marketing organizations is also much welcomed by Texas hospitals.

4. Behavioral Health Access in Medicare Advantage

Recommendation: THA ***strongly supports*** CMS' proposals to improve behavioral health access for Medicare Advantage beneficiaries.

Background

THA applauds CMS for its 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, we 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.

THA supports 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. 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.

5. Overpayment Enforcement & Revision of Legal Standard

Recommendation: THA **opposes** CMS' proposal to amend the legal standard for identifying overpayments from "reasonable diligence" to the False Claims Act definition of "knowingly" as it would significantly alter the ability of hospitals to correctly identify overpayments, exposing them Texas hospitals to False Claims Act liability even if they are acting in good faith.

Background

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. When Texas hospitals 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.

The 2016 Final Rule

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, 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.**

We particularly appreciate CMS's thoughtful proposals to improve how the Medicare Advantage 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.** If you have any questions, contact Anna Stelter, Senior Director, Financial Policy (astelter@tha.org) and Heather De La Garza, Assistant General Counsel (hdelagarza@tha.org).

Kind regards,

/s/ Heather De La Garza

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