February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

SUBJECT: CMS-4201-P, 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 (Vol 87, No 247), December 27, 2022

Dear Administrator Brooks-LaSure:

On behalf of our more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed policy and technical changes for the contract year (CY) 2024 Medicare Advantage (MA) program.

CHA applauds CMS for responding to longstanding stakeholder concerns about how Medicare Advantage Organization (MAO) practices and policies — in particular prior authorization practices — have impeded patient access to health care services, creating inequities in coverage between Medicare beneficiaries enrolled in MA versus those with traditional Medicare, and negatively impacting patient health outcomes due to unnecessary delays in care or denial of covered services.

Many policies in the proposed rule respond directly to comments CHA provided in response to CMS' August 2022 request for information (RFI) on Medicare and the CY 2023 MA proposed rule, including an RFI on hospital transfers to post-acute care settings during the COVID-19 public health emergency.

We are pleased to see our members' experiences reflected in the proposed rule and thank CMS for taking steps to ensure Medicare beneficiaries receive the services they are entitled to, regardless of their enrollment in traditional Medicare or MA.

Overall, CHA generally supports the policies included in the proposed rule, which will expand access to behavioral health and ensure MA beneficiaries have access to the same benefits and services as patients

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with traditional Medicare. CHA appreciates that CMS is responding to stakeholder concerns about these access challenges for MA beneficiaries by clarifying and codifying its policies into regulation. While CMS notes in the proposed rule that most of the proposed policies are existing requirements discussed in CMS guidance, such as the Medicare Managed Care Manual, our members' experience has shown that MAO practices have not been consistent with traditional Medicare policies. **As CMS codifies these existing policies in the final rule, we urge the agency to provide additional information on how it will exercise oversight of MAOs and enforce compliance with its regulations.**

Behavioral Health Specialties in MA Networks

Under current regulations, MAOs are required to demonstrate that they meet network adequacy for two behavioral health specialty types: psychiatry and inpatient psychiatric facility services. CMS proposes to add three new provider specialty types to be subject to network adequacy evaluations: clinical psychology, clinical social work, and prescribers of medication for opioid use disorder. CMS also proposes to establish specific time, distance, and minimum provider ratio network standards using the same analysis and steps that are used for existing specialty types.

CHA strongly supports CMS' proposal to add new behavioral health specialty types to the list of those subject to MA network adequacy requirements. The proposed additions will expand outpatient behavioral health and opioid treatment access to MA beneficiaries. However, under existing network adequacy requirements, studies have shown that narrow networks significantly limit MA beneficiary access to various specialties, with access to psychiatrists being the most restricted. For example, a report by the Kaiser Family Foundation found that MAOs included just 7% of Los Angeles County psychiatrists in their networks,[1] drastically limiting MA beneficiary access to serious mental health care treatment. **As CMS expands the specialty types subject to network adequacy requirements, we urge the agency to conduct appropriate oversight to ensure that MA networks are not so narrow that patients are unable to access the care they need.**

Behavioral Health Services in MA

CHA also strongly supports CMS' proposals to ensure access to behavioral health services is available to MA enrollees as part of the overall delivery and care of services. Specifically, we support CMS' proposal to add behavioral health services to the types of programs MAOs must have in place to ensure continuity of care and integration of services. It is essential that patients with behavioral health needs be able to access care without significant interruption in services, like when a provider leaves a network or isn't a good fit for the patient.

Additionally, we applaud CMS for clarifying that the definition of "emergency medical condition" includes both physical and mental conditions. Under current regulations, MAOs must reimburse a provider for emergency services without regard to prior authorization or the provider's contractual relationship with the MAO. However, the existing regulatory definition of "emergency medical condition" does not explicitly extend to both physical and mental conditions. CMS proposes to add language to definitively clarify that MA enrollees must receive access to medically necessary services in a mental health emergency. Specifically, CMS proposes to modify the regulatory definition at §422.113(b)(1)(i) to read: "Emergency medical condition means a medical condition, mental or physical, manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an

[1] https://files.kff.org/attachment/Report-Medicare-Advantage-How-Robust-Are-Plans-Physician-Networks

average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in."

CMS notes that under the current regulatory definition, one could reasonably expect that the absence of immediate medical attention to a behavioral health condition could cause serious injury or death, such as in a case of suicidal ideation. It is critical that psychiatric emergencies be treated with the same haste as other medical emergencies — not delayed or denied through pre-authorization or in-network contract requirements. We strongly support CMS' proposal, which will ensure that MA enrollees receive their medically necessary services.

MA Network Adequacy: Access to Services

Under statute and regulations, MAOs may establish provider networks but must ensure all services covered by Medicare are available and accessible under the plan. CMS says that it has historically interpreted these requirements to mean that if an in-network provider or service is unavailable or inadequate to meet an enrollee's medical needs, the MAO must arrange for the services outside of the plan provider network at in-network cost-sharing for the enrollee. It notes that this guidance exists in Chapter 4 of the Medicare Managed Care Manual.[2] However, CMS also notes that the current regulatory text at §422.112(a)(3) does not fully account for the statutory scope of an MAO's obligations in two key ways. First, the regulation refers to specialty care only — rather than all medically necessary covered benefits. And second, the maintenance of in-network cost-sharing with the MAO arranging care outside of the network is not clearly stated. As such, CMS proposes to revise the regulatory text to codify the statutory requirements and long-standing sub-regulatory guidance. **CHA strongly supports this proposal.**

California hospitals have long reported challenges with assisting MA enrollees in receiving post-acute care in appropriate settings due to the limited networks of MAOs. For example, one member hospital in Southern California recently reported significant delays in discharging a patient on a ventilator and feeding tube who required hemodialysis and needed post-inpatient hospital care in a long-term care hospital (LTCH), rather than a skilled-nursing facility (SNF). While the MAO plan eventually approved the LTCH level of care, discharge was further delayed because the MAO did not have a contract with an LTCH and was unable to reach an agreement with one on a payment rate. The patient remained in the hospital for several weeks beyond the planned discharge date, until the patient's condition improved enough that they could be transferred to an in-network SNF. **We urge CMS to further clarify that it is the MAO's responsibility to ensure medically necessary care is provided in a timely manner, even when care must be accessed out of network.**

We also urge CMS to establish a provider complaint mechanism that would allow clinicians, case managers, and discharge planners to report MAO behavior that potentially violates these requirements. Providers have experience on an individual level — as well as with MAOs that operate in their market for all patients — and are likely to recognize patterns of inappropriate delays and denials from the MAOs. Unfortunately, there is currently no streamlined way for providers to flag these patterns for regulators. We encourage CMS to create a mechanism to facilitate provider complaints and raise concerns that could guide heightened enforcement of MAO requirements.

[2] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf#page=79

Utilization Management Requirements

Coverage Criteria for Basic Benefits

CHA applauds CMS for proposing several policies that would codify standards for coverage criteria into regulation, ensuring that basic coverage benefits for MA enrollees are no more restrictive than under the Medicare fee-for-service (FFS) program. Our members have long reported significant challenges with MAOs denying coverage for services or in-care settings that are available to patients with traditional Medicare benefits. These include denials for medically necessary inpatient admissions or discharges to post-acute settings such as LTCHs or inpatient rehabilitation facilities (IRFs). As indicated by the Department of Health and Human Services' Office of Inspector General's (OIG) April 2022 report,[3] MAOs frequently use medical necessity and coverage criteria that are more restrictive than traditional Medicare, resulting in added burdens for providers who divert resources from direct patient care and adversely impacting health outcomes for MA enrollees.

Specifically, CMS proposes to clarify at §422.101(b)(2) that statutes and regulations that set the scope of coverage in the Medicare FFS program apply to MAOs in setting the scope of basic benefits that must be covered by MA plans. CMS also proposes to revise the regulation to provide examples of FFS coverage criteria for different circumstances — listing inpatient admissions, SNF care, home health services, and IRFs. This would clarify that those criteria apply to coverage of basic benefits for MA plan enrollees.

CHA strongly supports this clarification, and we appreciate that in the preamble language, CMS describes its list of examples as "not exhaustive." However, we urge CMS to further clarify its regulatory language by including the example of a LTCH as within the scope of traditional Medicare basic benefits that must be available for MA enrollees. CHA members report that MAOs often deny care for LTCH settings. These settings are a covered Part A benefit and specialize in providing care to patients with more than one serious medical condition who are hospitalized for 25 days or more. It is our members' experience that MAOs deny this level of care in favor of less-expensive SNF settings, which are not equipped to provide the level of long-term acute care that these patients need.

CHA also supports CMS' proposal to specify that when making coverage determinations on a Medicare-covered item or service, MAOs may not deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in traditional Medicare FFS coverage policies. As proposed, the use of clinical treatment guidelines that require another item or service to be furnished prior to receiving the requested item or service would be prohibited. That is, unless the use was permitted by Medicare statute, regulation, or by a national coverage determination (NCD) or local coverage determination (LCD). CMS further clarifies that this expectation applies at all times, meaning both before and after the provision of the item or service as well as during treatment. It reiterates that the proposals also apply to substantive coverage criteria and benefit conditions found in Medicare FFS regulations, such as those for inpatient admissions and transfers to post-acute care settings, which are not governed by an NCD or LCD. CHA appreciates this clarification, along with CMS' many examples in

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

the proposed rule related to illustrating how MAOs cannot limit when or where care is provided in post-acute care settings that would be covered by traditional Medicare.

We also interpret the proposed language to clarify that Medicare policies like the two-midnight rule must be followed by MAOs. That rule establishes that inpatient admissions would generally be payable under Part A if the admitting practitioner expected the patient to require a hospital stay that crossed two midnights, with a medical record supporting that reasonable expectation. **We urge CMS to explicitly clarify in the final rule that MAO plans must follow the two-midnight standard when supported by the medical record.**

CMS further proposes that when coverage criteria are not fully established by Medicare statute, regulations, or by an NCD or LCD, MAOs would be permitted to create internal coverage criteria that are based on current evidence in widely used treatment guidelines or publicly available clinical literature. In creating these internal policies, MAOs would have to provide publicly available information detailing the factors the MAO considered in making coverage criteria for medical necessity determinations, which is similar to the process used for NCDs. Examples include a summary of the evidence considered, a list of sources, and an explanation of the rationale for the criteria. **CHA has long called for transparency into MA plans' internal coverage criteria and we strongly support this proposal.**

Appropriate Use of Prior Authorization

CMS notes that, generally, MAOs may impose prior authorization requirements for basic benefits — except in the case of emergency services, urgently needed services, stabilization services, and out-of-network services covered by MA preferred provider organization plans. To better clarify its policies, CMS proposes new regulatory text at §422.138 that would specify how and when prior authorization may be used by coordinated care plans. Specifically, coordinated care plans could only use prior authorization in connection with basic benefits or supplemental benefits for one or more of the following purposes:

- To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service
- For basic benefits, to ensure an item or service is medically necessary based on standards for coverage criteria discussed above
- For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate

CMS also proposes that if the MAO approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it could not deny coverage later based on lack of medical necessity. However, it could deny that coverage under those circumstances if the MAO has the authority to reopen the decision for good cause, fraud, or similar fault pursuant to the reopening provisions. **CHA strongly supports these proposals, which will ensure that hospitals are reimbursed for medically necessary care, and that patients are not left with unexpected costs following an approved service. However, as noted in our earlier comments, we urge CMS to establish**

a provider complaint mechanism that would enable hospitals to report patterns of inappropriate plan denials for previously approved services.

Continuity of Care

Current regulations require that MAOs offer coordinated care plans to ensure continuity of care and integration of services through arrangements with contracted providers. CMS proposes two additional continuity of care requirements for the use of prior authorization for basic benefits provided by coordinated care plans. Specifically, CMS proposes that MAOs offering coordinated care plans that use prior authorization for basic benefits would be required to treat approval of a prior authorization request as valid for the duration of the prescribed and approved course of treatment. Additionally, MAOs would have to provide for a minimum 90-day transition period for any active course of treatment when an enrollee is in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. **CHA strongly supports these proposals, which will avoid redundant and disruptive prior authorization requests and ensure a patient receives appropriate care even if transitioning between plans.**

Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee

CHA supports CMS' proposals to require the establishment of a UM committee and specific processes for the annual review of all UM policies and procedures, including prior authorization. The review would call for approval of those UM policies and procedures, a revision of existing UM policies and procedures to comply with the new proposed requirements, and documentation of the rationale for its decisions. The establishment of this committee would provide another layer of transparency where MAOs would have to demonstrate compliance with the proposed requirements that ensure MAO coverage policies are no more restrictive than those for traditional Medicare.

We also strongly support CMS' proposals to require that the UM committee include at least one practicing physician who is independent and free of conflict — relative to the MAO and MA plan. We also support the requirement that at least one practicing physician be an expert regarding the care of elderly or disabled individuals. The care of older adults and individuals with disabilities requires a unique perspective. It's one that recognizes that their health care needs tend to be more complex, they frequently co-occur with one or more chronic diseases or co-morbidities, and are often associated with a decline in functional independence. While many medical interventions (and specific physician disciplines) can treat acute illnesses, successful medical outcomes for older adults and persons with disabilities must also incorporate these other elements into the care plan. In recent years, we've seen increasing recognition of the specialized needs of older adults, with the advent of more "age-friendly" health care in hospitals and other health care settings.

If finalized, this policy would help to address provider concerns about access to post-acute care, particularly inpatient acute rehabilitation. Our member hospitals report that many MA plans routinely deny access to IRFs or LTCHs, even when patients clearly meet medical necessity criteria. That's because the plan personnel who make the determinations, including physician reviewers, often have a limited understanding of these levels of care. As a result, patients who require treatment at an IRF or LTCH are denied access to the care that will best meet their needs and maximize their ability to return to the highest possible level of independence. An inappropriate diversion to the wrong setting of care and lack

of access to rehabilitative services can determine whether an individual is able to successfully return to their home and community or remain in a SNF on a long-term basis.

It is critical that UM criteria for medically necessary, post-acute care services be developed, implemented, and reviewed with meaningful input from physicians with expertise in the continuum of care and the ongoing care of older adults and persons with disabilities. Rehabilitation physicians (physiatrists) and geriatricians specialize in this type of care and are acutely aware of the integral role that mobility and functional status play in achieving and maintaining optimal medical outcomes and quality of life. As such, their expertise is particularly valuable in integrating the determination of ongoing goals of care and the impact of co-existing conditions for UM policies that identify the most medically appropriate level of post-acute care.

Termination of Services in Post-Acute Care

CMS seeks comments in response to concerns over reports of early termination of services in post-acute care settings. CHA shares these concerns, as MA plan policies often unnecessarily disrupt patients' post-acute care plans with repeated requests for prior authorization in very short increments. This is both cumbersome for providers and leads to uncertainty that impacts care planning and ultimately clinical outcomes for patients. CHA would support policies that strengthen patient appeal rights for termination of these services. That would include requiring MAOs to provide enrollees with information on the basis for termination of service decisions (e.g., the clinical rationale for termination of services) as part of the termination notice and without the enrollee having to request an appeal to the quality improvement organization (QIO). We would also support a policy that would give enrollees more than the two-day period from the date of a new termination of services notice before coverage can be terminated again by the MAO, considering any medical necessity determinations made by the QIO.

The nature of post-acute care is such that care plans and goals are developed and administered over time, often in the range of two to four weeks. For example, upon admission to an IRF, the clinical team will identify goals for medical and functional status and identify a tentative discharge date. The discharge plan will be predicated on the patient's anticipated care needs at that time. Some MA plans do not recognize this and routinely require frequent reauthorization, with the potential of continued stay denials at any time. While CHA recognizes the need for ongoing communication between the facility and the plan, frequent reauthorization places undue burdens on the facility and diverts resources from direct patient care. More importantly, care teams will be unable to develop and implement successful discharge plans without a clear understanding of the discharge date and anticipated time frame for the achievement of the patient's care goals.

For this reason, CHA urges CMS to specify that plans are required to provide prior authorization for the full episode of care, as established by the clinical team under the direction of the responsible physician. If the care plan proceeds as indicated, additional reauthorizations should not be required. Should the patient's clinical needs change, a revised episode of care and discharge date should be established by mutual agreement. In any case, plans should be prohibited from terminating

reimbursement for a post-acute care stay with less than a 72-hour notice, to allow sufficient time for revised discharge planning needs.

Review of Medical Necessity Decisions by a Physician or Other Health Care Professional with Expertise

Under current regulations, MA plan reconsiderations related to coverage denials that are based on medical necessity determinations must be made by a physician with appropriate expertise in the applicable field of medicine. Additionally, the physician reviewer must be different from the physician or other health care professional involved in the initial determination. However, the statute does not currently specify who must conduct the initial medical necessity determinations. Rather, CMS requires MAOs to have appropriate health care professionals "with sufficient medical and other expertise, including knowledge of Medicare coverage criteria," review initial determinations involving issues of medical necessity.

CMS proposes to refine the current regulation by adding a requirement. The physician or other appropriate health care professional who conducts the initial review must have expertise in the appropriate field of medicine for the item or service being requested. That would occur before the MA organization or applicable integrated plan issues any potential adverse organization determination decision. CMS would not require that the reviewing physician or other appropriate health care professional, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. **CHA strongly supports this proposal, which will align initial determination requirements with the existing standard at the reconsideration level. As demonstrated by a 2018 OIG report,[4] a significant number of adverse medical necessity determinations are ultimately overturned on appeal, and aligning expertise requirements of initial determinations with reconsideration decisions should prevent some inappropriate denials.**

Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act

CMS proposes to change the 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. Specifically, the proposed rule would remove the following language at 42 C.F.R. § 401.305(a)(2):

- A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and *quantified the amount of the overpayment.*[5] A person should have determined that the person received an overpayment *and quantified the amount of the overpayment*[6] if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

This removed language would be replaced with the new proposed 42 C.F.R. § 401.305(a)(2):

- A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

The proposed change appears to result from litigation related to the Medicare Part C and D overpayment rule (*UnitedHealthcare Ins. Co. v. Becerra*). In this case, a federal court determined that CMS' incorporation of "reasonable diligence" to investigate an overpayment in the Part C and D rule was

[4] https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf
[5] Emphasis added
[6] Emphasis added

outside the agency's rulemaking authority under the overpayment statute. However, the cited case did not specifically address limiting the time period necessary to quantify the amount of an overpayment to 60 days. Therefore, any implication that CMS is now required to modify the standard of when an overpayment is identified is inaccurate.

CMS attempted a similar approach to the one in the initial proposed rule[7] related to Medicare overpayments in 2012. That approach would have required repayment within 60 days of having identified an overpayment, without allowing for sufficient time for quantification of the overpayment. However, the final rule[8] promogulated by the agency in 2016 acknowledged the impracticality of requiring hospitals and other providers to repay an overpayment within 60 days of its identification. In a reasoned change from the 2012 proposed rule, the final rule tolled a 60-day clock from the point in time when the overpayment amount was quantified. By doing so, CMS implicitly acknowledged that tolling the 60-day clock from the point in time when the overpayment amount is quantified is a more accurate reading of section 6402 of the Affordable Care Act.

The practical effect of this change — if finalized — requires that Part A and Part B overpayments be reported and returned within 60 days of the provider or supplier having actual knowledge, or being in reckless disregard or deliberate ignorance, of the existence of the overpayment. However, CMS does not address the material challenges this new, unrealistic requirement will present to hospitals and providers. Specifically, the rule does not provide details on how a hospital or provider can return an overpayment within 60 days if its existence is known, but the amount of overpayment has not been fully quantified.

As CMS is aware, claims investigations will differ depending on the type and size of the provider and/or the nature of the billing irregularity. In certain situations, billing investigations could require the analysis of hundreds, or possibly thousands, of claims, often with some manual component required as part of a thorough review. Quantifying the overpayment within 60 days could be impossible if the issue requires a detailed review of patient medical records to determine if an overpayment occurred and, if so, how much of an overpayment occurred. A detailed review of patient charts is not an uncommon step and would be required in a variety of potential overbilling scenarios. Those could range from questions about the medical necessity of services provided to the accuracy of diagnosis codes submitted for risk adjustment purposes.

CMS should not impose an unrealistic 60-day deadline on hospitals and health systems to return overpayments once they identify an overpayment. Instead, once hospitals and health systems know of the existence of an overpayment, the U.S. Department of Health and Human Services should allow hospitals to calculate the amount that must be repaid before any 60-day clock is tolled. Based on rules of statutory construction and legislative history, there is good evidence that the agency's current proposal far exceeds what Congress intended when it enacted this provision with the Affordable Care Act. **Therefore, CHA urges CMS to give providers the necessary flexibility to analyze the breadth and scope of the billing error and to investigate, articulate, and quantify overpayments with reasonable certainty.** This is essential, particularly given the harsh consequences of billing errors that are not repaid within 60 days.

[7] 77 FR 9179, CMS–6037–P: Medicare Program; Reporting and Returning of Overpayments, Feb. 16, 2012
[8] 81 FR 7654, CMS–6037–F: Medicare Program; Reporting and Returning of Overpayments, Feb. 12, 2016

CHA appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me at mhoward@calhospital.org or (202) 488-3742, or my colleague Chad Mulvany, vice president, federal policy, at cmulvany@calhospital.org or (202) 270-2143.

Sincerely,

/s/
Megan Howard
Vice President, Federal Policy