

February 13, 2023

Chiquita Brooks-LaSure Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services PO Box 8013 Baltimore, MD 21244 CMS-4201-P

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 Proposed Rule

Dear Administrator Brooks-LaSure:

On behalf of our 40,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on a rule that proposes changes to the Medicare Advantage (MA) and Medicare Prescription Drug (Part D) programs for contract year 2024. Specifically, we would like to address a few policies proposed in the rule that have a significant impact on emergency physicians and the patients we serve.

Ensuring Timely Access to Care: Utilization Management Requirements

Overall, ACEP appreciates and supports CMS' multiple proposals to streamline prior requirements. These proposals, if finalized, reduce unnecessary barriers to care and ensure that MA enrollees receive all the services that they are entitled to under Traditional Medicare in a timely manner. In most cases, emergency services are exempt from prior authorization. Every second counts when it comes to treating patients with potentially life-threatening conditions, and therefore, both public and private payors recognize how it unsafe and impracticable it would be to require patients in the emergency department (ED) to receive prior authorization before being able to receive critical services. However, as emergency physicians, we still see how prior authorization can affect the ability of our patients to receive the most appropriate treatment in the most appropriate care setting. We have experienced numerous occasions where patients who are unable to receive services in other care locations because of a prior authorization denial come to the ED to receive those services (sometimes at the direction of their provider). The patient comes to the ED because he/she and/or his/ her provider recognize that the patient can receive the service without undergoing prior authorization. This clearly is not an appropriate reason for a patient to receive treatment in the ED, but it reflects a fundamental flaw in the health care system resulting from extremely stringent prior authorization protocols.

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Unfortunately, prior authorization in MA is being frequently utilized, but in many cases, is not being used appropriately to avoid unnecessary care. Instead, it is *delaying necessary care*, which negatively impacts the health of Medicare beneficiaries. According to the <u>Kaiser Family Foundation</u>, there were 35 million MA prior authorization requests in 2021. Over 2 million prior authorization requests were fully or partially denied by MA plans, and 11 percent of those denials were appealed. The vast majority (82 percent) of appeals resulted in fully or partially overturning the initial prior authorization denial. Since MA plans are not required to indicate the reason a denial was issued in the reporting to CMS, it is unclear why claims are being denied. However, regardless of the reason, the fact that the majority of prior authorization denials that are appealed are fully or partially overturned gives credence to the argument that prior authorization is simply a delay tactic.

Prior authorization also affects ED care by contributing to ED "boarding," which is a situation where patients are kept in the ED for days (or longer) due to the lack of available inpatient beds or space in other facilities where the patient could be transferred. Boarding has hit crisis levels, and in November 2022, ACEP and 34 other organizations wrote a <u>letter</u> to President Biden asking his Administration to convene a summit on this issue with all impacted stakeholders so that we can together collaborate on near- and longer-term solutions.

ACEP has heard from many of our members that health plans are requiring prior authorization before a patient can be transferred from the hospital to a post-acute facility, like a skilled nursing facility. A key stakeholder in the ED boarding crisis, the American Hospital Association (AHA), pointed out in a March 2022 letter to CMS that the use of prior authorization among MA plans was clogging up inpatient beds. As the AHA states, the use of prior authorization is "especially problematic when general acute-care hospital beds have been filled to capacity and while health care providers contend with the demands of vaccine distribution and workforce shortages." The continued use of prior authorization has also "resulted in unintended consequences for patients who were then forced to stay in acute care settings unnecessarily while waiting for health plan administrative processes to authorize the next steps of their care."

The AHA asked CMS in the letter to prohibit MA plans from conducting prior authorization at least during the remainder of the COVID-19 pandemic. CMS did not adopt such a policy, and hospitals have become even more filled with patients since then, which in turn has caused longer ED wait times and more boarding in the ED, as individuals have to wait for extended periods (multiple days or even longer) for inpatient beds to become available.

In this proposed rule, CMS makes it clear that MA plans cannot deny coverage for services that are covered by Traditional Medicare, but the agency still allows prior authorization to take place in most instances (except for emergencies). With respect to the issue of transferring patients from hospitals to post-acute facilities, CMS states that MA plans cannot deny a transfer if the post-acute services a patient would receive align with Traditional Medicare coverage criteria. However, CMS still says that prior authorization is allowed in these circumstances to "ensure items and services meet Medicare coverage rules; it simply limits the coverage criteria that an MA organization can apply to deny an item or service during those reviews." ACEP believes that this proposal does not go far enough, and that CMS should in fact prohibit MA plans from requiring prior authorization in order to transfer patients to post-acute facilities. We believe that policy could be one short-term solution that could help address the boarding crisis.

¹ Fed. Reg. Vol. 87, 79501, (December 27, 2022).

Medical Necessity

CMS is proposing to codify the regulatory requirement that MA organizations must make medical necessity determinations based on coverage and benefit criteria included in Traditional Medicare. Medical necessity is <u>defined in Medicare</u> as "health care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." Although there are currently protocols and standards in place to appropriately document medical necessity in the ED, ACEP asserts that care delivered in the ED is *inherently medically necessary*—specifically due to two existing and long-standing federal laws pertaining to emergency care that require the delivery of diagnostic services and stabilizing care: the Emergency Medical Treatment and Labor Act (EMTALA) and the Prudent Layperson Standard.

EMTALA requires hospitals to provide a medical screening examination to every individual who "comes to the emergency department" seeking examination or treatment. The patient protections and federally required standard of evaluation and stabilization in the ED fundamentally establishes medical necessity.

With respect to the Prudent Layperson Standard (discussed more in the next section of the response), payors cannot deny reimbursement to providers based on the patient's final diagnosis. An "emergency" versus a "non-emergency" must be determined on a case-by-case basis based on whether the patient's symptoms and complaints reasonably represented to them as a prudent layperson a potential emergency condition. In all, if the Prudent Layperson Standard applies (which happens almost all the time), ACEP strongly believes that the care provided to patients meets the requirements of medical necessity and therefore, should be covered by MA plans and other insurers.

Lastly, we strongly support CMS' proposal to require the physician or other appropriate health care professional who conducts a medical necessity review to have expertise in the field of medicine that is appropriate for the item or service being requested before the MA organization can issue an adverse determination decision. While we believe that all care provided in EDs are medically necessary, if there are any questions about medical necessity related to ED care, an evaluation within an MA organization must be conducted by a board-certified emergency physician.

Definition of Emergency Medical Condition

As alluded to earlier, MA organizations are required to reimburse a provider for emergency services without regard to prior authorization or the emergency care provider's contractual relationship with the MA organization. An "emergency medical condition" is defined as a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in serious jeopardy to the health of the individual or their unborn child, serious impairment to bodily function, or serious dysfunction of any bodily organ or part," However, CMS notes in the proposed rule that the definition does not explicitly extend to both physical and mental conditions.

CMS believes both physical and mental health cases satisfy the prudent layperson standard, therefore immediate emergency medical intervention must be provided without regard to prior authorization. Therefore, CMS proposes to add language to their regulations that will definitively clarify that an emergency medical condition can be physical or mental in nature. CMS believes that this regulatory change will ensure that enrollees have access to emergency behavioral health services in parity with access to other medical emergency services.

ACEP <u>STRONGLY SUPPORTS</u> this modification to the regulation and agrees wholeheartedly with CMS that an emergency medical condition includes both physical and mental health emergencies and that the prudent layperson standard protection should be attributable to all types of emergencies. We note that such a policy aligns with emergency physicians' oath and duty to serve our patients. As emergency physicians, we appreciate our essential role in strengthening the health care safety net for our communities. We treat all patients who come through our doors, regardless of their insurance status or ability to pay—and this includes individuals suffering from both physical and mental health emergencies.

We also urge CMS to ensure that the revised definition of emergency medical condition and the prudent layperson standard is appropriately enforced. Unfortunately, many private plans, including MA plans and Medicaid Managed Care organizations, are routinely violating the prudent layperson standard. Unfortunately, ED claims are denied by insurers due to a "lack of medical necessity" after seeing a final diagnosis. **Again, we strongly believe that such a denial represents a fundamental violation of the prudent layperson standard**. Patients with symptoms consistent with a possible emergency health condition should not be expected to self-diagnose before making a decision as to whether to come to the ED.

Even as experienced emergency physicians, we cannot determine a patient's final diagnosis (or whether they have an emergency or non-emergent medical condition) based on the patient's symptoms when they first present to the ED. Many conditions share very similar symptoms, and a full work-up and examination is frequently required (sometimes with additional diagnostic tests) before the ultimate diagnosis becomes clear. In fact, a 2013 peer-reviewed study published in JAMA of over 34,000 ED visits found that for those discharge diagnoses which could be considered primary care—treatable, the chief complaints reported for these visits were identical to those reported for 88.7 percent of all of the studied ED visits, many of which ended up requiring admission to the hospital, triaged at the highest/most urgent level, or went directly to the operating room.

The extremely limited concordance between presenting complaints and ED discharge diagnoses in this study demonstrates that using lists of diagnostic categories as a means for making coverage determinations is a flawed and inaccurate practice. It is medically necessary to apply appropriate diagnostic and treatment methods for patients' presenting symptoms. Failure to do so would not meet accepted standards of care and pose serious risk for patients.

Thus, in all, while we appreciate this acknowledgement and strengthening of the prudent layperson standard, it is equally important to that CMS enhance its enforcement of this vital patient protection.

Protecting Beneficiaries: Marketing Requirements

In the proposed rule, CMS lays out numerous ways in which MA plans are engaging in misleading and false advertising practices, resulting in seniors enrolling in plans that do not meet their health care needs and/or were more costly than they had been led to believe.

ACEP applauds CMS' efforts to crack down on these fraudulent practices and supports all the proposals in the rule meant to address this issue. It is critical that seniors receive accurate information and fully understand their coverage options. If individuals enroll in a more expensive plan than they can afford, they may wind up delaying necessary care and, after their disease has progressed, be forced to go to the ED to seek treatment. MA plans must therefore be held fully accountable for such behavior.

The MA market in general has become heavily concentrated among large, nation-wide insurance companies. According to an <u>article in Modern Healthcare</u>, in 2022 seven national health insurance companies claimed nearly 70 percent of Medicare Advantage (UnitedHealthcare, Humana, Aetna, Anthem, Centene, Cigna, and Molina). These large organizations are making significant profits, and unfortunately are doing so in part due to false marketing and billing practices. CMS must continue to implement policies such as the ones included in this proposed rule to protect Medicare beneficiaries and ensure that they are receiving the health care coverage and care that they need.

Network Adequacy and Behavioral Health Services.

CMS proposes policies to strengthen network adequacy requirements and reaffirm MA organizations' responsibilities to provide behavioral health services. Specifically, CMS proposes to:

- Add Clinical Psychologists, Licensed Clinical Social Workers, and Prescribers of Medication for Opioid Use
 Disorder as specialty types for which CMS sets specific minimum standards and on which CMS evaluates MA
 networks, and make these specialty types eligible for the existing 10 percentage point telehealth credit;
- Amend general access to services standards to explicitly include behavioral health services;
- Codify standards for appointment wait times for both primary care and behavioral health services;
- Require that MA organizations notify enrollees when the enrollee's behavioral health or primary care provider(s) are dropped midyear from networks; and
- Require MA organizations to establish care coordination programs, including coordination of community, social, and behavioral health services to help move towards parity between behavioral health and physical health services and advance whole-person care.

ACEP strongly supports these proposals to enhance access to behavioral health services. In general, we have long advocated for CMS to enforce strong network adequacy standards across both Medicare and Medicaid as a way to ensure that all Medicare beneficiaries and Medicaid enrollees have access a full range of health care services. However, we believe that as a way to enhance access to emergency behavioral services, CMS must add emergency medicine to provider specialty list for MA plans. We believe that it is essential for all beneficiaries enrolled in MA to know from their MA health plan in advance of an emergency if the emergency physician treating them is in-network (NOT during or after an emergency has occurred). The very nature of ED care, more than any other type of specialty care, precludes the opportunity for patients to preferentially go to facilities with in-network emergency physicians.

Ensuring Equitable Access to MA Services

Currently, MA organizations that offer coordinated care plans are required to ensure that services are provided in a culturally competent manner to all enrollees, including those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds. CMS is proposing to expand this list include (i) people with limited English proficiency or reading skills; (ii) people of ethnic, cultural, racial, or religious minorities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in rural areas and other areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality. ACEP strongly supports this proposal and agrees with CMS that this expansion will help promote health equity within the Medicare program.

MA Provider Directories

To further enhance CMS' requirements for MA provider directories in the area of behavioral health, CMS proposed to add a new required provider directory data element for certain providers who offer medications for opioid use disorder (MOUD). CMS proposes to require organizations to identify certain providers in their provider directories who have obtained a waiver. ACEP applauds the concept of this proposal, since we strongly support the use of MOUD for the treatment of OUD, but believe that it is no longer necessary, since the X-waiver was repealed by Congress through the passage of the *Consolidated Appropriations Act, 2023* (Pub. L,117-328, December 29, 2022). However, we still believe that CMS should finalize a similar requirement that will help enrollees know where they can access this life-saving treatment.

Telehealth Literacy

CMS acknowledges the growth in the use of telehealth, but also points that there are significant barriers to its use, including: lack of video sharing technology (for example, a smartphone, tablet, or computer), spotty or no internet access, lack of housing or private space to participate in virtual visits, few local providers who offer telehealth practices, language barriers (including oral, written, and signed language), the inability to incorporate third party auxiliary aids and services such as live captioners, telehealth software, apps, and websites that are accessible and usable by people with disabilities, and lack of adaptive equipment for people with disabilities along with incompatibility with external assistive technologies used by people with disabilities. ACEP definitely agrees with CMS that the existence of communities with low digital health literacy who in turn cannot access telehealth represents a significant obstacle in achieving health equity in telehealth. Therefore, we strongly support CMS' proposal to add requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory and External Affairs, at idavis@acep.org.

Sincerely,

Christopher S. Kang, MD, FACEP

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ACEP President