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May 16, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to urge the Centers for Medicare & Medicaid Services (CMS) to take a holistic approach to reforming prior authorization (PA). The AMA is encouraged by our recent conversations with CMS staff in which there was mutual agreement that more must be done by the federal government to address shortcomings in PA used by Medicare Advantage (MA) plans. **Yet, absent CMS confronting both the PA *process* and the PA *decision-making* used by MA plans, we fear more patients will be harmed, and physicians will struggle with an overwhelming amount of administrative burden.** New data has also shown that minority beneficiary enrollment in MA is higher than ever before. Nearly 44 percent of Hispanic Medicare beneficiaries and over 31 percent of African American Medicare beneficiaries are enrolled in MA plans. Data show an increasing trend in minority enrollment.[1] For this reason, PA and denials by MA plans have a bigger impact on historically minoritized Medicare patient populations. The AMA supports your efforts to prioritize health equity, and we urge you to consider the health equity implications of PA.

On April 27, 2022, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) released a report detailing concerns about beneficiary access to medically necessary care administered by Medicare Advantage Organizations (MAO).[2] In its report, the OIG stated that MAOs are denying PA and payment requests that met Medicare coverage rules by using MAO clinical criteria that are not contained in Medicare coverage rules, requesting unnecessary documentation from physicians, and making manual review and system errors. The OIG's report mirrors physician experiences. Surveys of physicians have consistently found that the payers' PA decision-making is persistently responsible for serious harm when necessary medical care is delayed, denied, or disrupted. Nearly a third of physicians report health plans rarely or never use evidence-based criteria in their PA programs, and 91 percent of physicians report a negative impact on clinical outcomes due to the PA process. **Most shockingly, 34 percent of physicians report PA has led to a serious adverse event for a patient in their care—with nearly one in 10 physicians reporting PA has led to patient disability/permanent bodily damage, congenital anomaly/birth defect or death.**[3]

[1] https://bettermedicarealliance.org/blog-posts/advancing-health-equity-in-medicare/.
[2] https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.
[3] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

A set of technical tools and guides are on the horizon to assist in the exchange of information between physicians and payers. The Health Level Seven (HL7) Da Vinci guides could assist in reducing the manual processes payers use to administer PA. The AMA recognizes the potential of these guides and is active in HL7's efforts to move this technology forward. Removing the burden of manually engaging in PA cycles with payers, e.g., using online portals and faxes, is a part of needed PA reform. Yet, and as recognized by CMS staff, the HL7 electronic prior authorization (ePA) effort is focused on automating the process of requesting, identifying, and exchanging information necessary for PAs. While this may reduce some friction between physicians and MAOs, ePA does not address the decision-making used by MAOs. It is the MAO's decision-making that the OIG identified as causing harm to patients. Consider these two examples cited by the OIG:

Request: MRI of abdomen

Case: A 65-year-old had a history of chest pain that radiated to the shoulder and left jaw. The beneficiary had a previous MRI showing two adrenal lesions of indeterminate origin, the largest of which was 1.5 cm.

Denial: The MAO denied the request (after requesting and not receiving additional records) stating that the beneficiary would need to wait at least one year for another MRI given the size of the largest lesion. The MAO cited internal clinical criteria that allowed follow-up MRIs only at 12 months for a lesion of 1-2 cm in size or at 6-12 months for lesions greater than 2-4 cm in size. A health care coding expert determined that the applicable NCD does not restrict the timing of MRIs based on the size of the lesion. Furthermore, using clinical information already in the case file, the physician panel stated the MRI was medically necessary to determine whether the lesions seen on the CT scan were malignant.

Reason: Applied MAO clinical criteria not in Medicare coverage rules and required unnecessary documentation
Outcome: Denial reversed upon appeal
Cost: $300

Request: A walker

Case: A 76-year-old had a history of joint pain, post-polio syndrome, ankle and foot surgery, and was at-risk for falls.

Denial: The MAO denied the request and cited internal clinical criteria, stating that the beneficiary was not eligible to receive a walker because the beneficiary had already received a cane within the past five years. The internal clinical criteria considered a cane and walker to be "same or similar" devices and limited beneficiaries to one such device every five years. However, according to our physician panel, a cane was not stable enough given the beneficiary's history of polio and arthritis, fall risk, and physical therapy notes that the right knee buckled and the right shoulder was in pain. Further, our health care coding expert determined that the LCD for walkers did not include a five-year restriction on more than one ambulatory device.

Reason: Applied MAO clinical criteria not in Medicare coverage rules
Outcome: Not reversed
Cost: $112

In both examples, the OIG identified that it was the MAO's decision to misuse or misapply coverage rules, as part of the MAO's PA decision-making, that resulted in delays or denials of care and patient harm. MAO PA decision-making disproportionately harms those with disabilities or chronic illness. Barriers to care impact patients who are sicker, need medical devices, or inpatient rehabilitation services—further undermining efforts to advance health equity in MA.

Yet, ePA alone cannot curb patient harm, delays in care, and physician burden. ePA simply automates PA processes used by payers today and is not designed to address delinquencies in MAO decision-making. Moreover, there are fundamental ePA problems that must be addressed prior to its use across physician practices. For example, a technical component of the Da Vinci ePA guides allows a payer to redirect an unlimited number of electronic PA requests from the electronic health record workflow to online portals, phone calls, and faxes. This is driven by ePA's anemic requirements on payers. Payers may also mark an unlimited number of ePA requests as "pending," resulting in additional delays and harms to patients. AMA has serious concerns that ePA by itself will make it easier for MAOs to abuse coverage rules—getting to "no" faster and automating patient harm. **As part of CMS' PA reform effort, we strongly urge CMS to review and reconsider the *decision-making* and *processes* used by MAOs and to ensure ePA is a sufficiently mature functional technology.**

We are encouraged by our shared desire to eliminate patient harm, delays in care, and physician burden associated with PA. Success in PA reform means always centering on the needs of patients and their well-being. We are also encouraged that CMS is in complete agreement here. We therefore urge CMS to act using a variety of policymaking levers, as outlined in the OIG report, to bring about needed reforms. CMS should develop MAO guidance on the appropriate use of MA clinical criteria, direct MAOs to revise and publish procedures for making coverage determinations, and require MAOs to identify and address PA system vulnerabilities. While the OIG report stated that CMS has agreed with these recommendations, we are troubled that the OIG's report also stated that CMS was made aware of these issues in 2018 and as of March 2022, CMS had not yet implemented these recommendations. **We urge you to direct all necessary internal CMS departments and staff to coordinate on an agency-wide campaign to reform PA.** We reiterate that PA reform will require addressing both the PA process and PA decisions made by MAOs. The AMA will continue its active engagement with CMS staff, monitor PA efforts as they arise, and provide assistance.

In closing, I want to thank you for this opportunity to provide the AMA's feedback and offer assistance in PA reform. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD