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The Honorable Seema Verma  
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

Re: Prior Authorization

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express concern over a recent report on the topic of prior authorization (PA) prepared for the Centers for Medicare & Medicaid Services (CMS) by the Government Accountability Office (GAO). In this report, titled “CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending,” the GAO recommends that CMS continue PA by extending current demonstrations and expanding PA to additional items and services to decrease program costs. The AMA believes that the GAO report minimizes the negative impacts of utilization management programs such as PA on health care. **We urge CMS to not follow the report’s recommendations, but rather carefully consider the care delays associated with PA and the resulting impact on beneficiaries and their health and well-being when evaluating any additional PA requirements for the Medicare program.**

PA programs can create significant treatment barriers by delaying the start or continuation of necessary treatment, which may in turn adversely affect patient health outcomes. For example, a Medicare beneficiary waiting for a power mobility device could experience a fall, leading to devastating and permanent consequences for the patient’s quality of life and overall health. Similarly, delaying medically necessary hyperbaric oxygen could lead to tissue loss or even loss of limb. Beyond the obvious potential for long-term clinical harm, Medicare beneficiaries, their families, and their caregivers can experience unnecessary stress and emotional duress while waiting for approval of medically necessary care. While these examples of services and items covered by current Medicare demonstrations may generally be characterized as non-emergent, we strongly believe that the care delays associated with PA could negatively impact the quality of care and patient clinical outcomes—with even graver consequences if Medicare PA requirements are extended to more urgent treatments.

Additionally, the very time-consuming processes used in these programs also burden physicians and other health care professionals and divert valuable resources away from direct patient care. We applaud CMS’ Patients Over Paperwork initiative and believe that the recommendations of the GAO report directly undermine CMS’ stated goal to reduce administrative burdens, increase efficiencies to improve patient care, and remove regulatory obstacles that prevent physicians from spending more time with patients. **We**

**again recommend that CMS carefully weigh any theoretical program savings from expanding PA as recommended in the GAO report against the negative impact on Medicare beneficiaries, physicians, and other health care professionals.**

### **Impact of PA on Patients**

Our principal concern with the course of action suggested by GAO is the potential effect on Medicare beneficiaries' ability to receive quality, timely care. To quantify the impact of PA requirements on both patients and physicians, the AMA conducted a survey of 1,000 practicing physicians in December 2017.<sup>1</sup> The survey found that 64 percent of surveyed physicians reported waiting at least one business day for PA decisions from health plans, while 30 percent reported waiting at least three business days. Not surprisingly, 92 percent of physicians said that PA can delay access to necessary care. These delays may have serious implications for patients and their health, as 78 percent of physicians reported that PA can lead to treatment abandonment, and 92 percent indicated that PA can have a negative impact on patient clinical outcomes.

The AMA has collected stories from both physicians and patients around the country to learn more about how prior authorization affects patients; these stories speak for themselves:

- “I recently had a patient die due to needing a prior authorization for cefpodoxime axetil for a UTI.”
- “I am a nurse practitioner. I see this every day, in many different ways. One of the biggest problems I face is that one insurance company has made it a policy that they will not approve liquid antibiotics for anyone over the age of 11. I have several patients with G-tubes that cannot swallow. I have to do a prior authorization every time to get liquid antibiotics.”
- “Do I hold my breath while waiting 3 days to breathe with inhalers? It's like a game of chess.”
- “It isn't wise and it isn't fair to add this burden to patients and their families, because living with and managing chronic illness is already fraught with many barriers. I am so exhausted.”<sup>2</sup>

We observe that the GAO report captures the troubling care delays associated with PA in its review of the CMS PA demonstrations for power mobility devices, repetitive scheduled non-emergency ambulance services, non-emergency hyperbaric oxygen therapy, and home health services. As noted in the report, CMS specified that Medicare Administrator Contractors (MACs) must review initial PA requests for items and services addressed by the demonstrations within 10 business days and make determinations on PA resubmissions within 20 business days. By the very nature of the program design, Medicare beneficiaries have been forced to wait weeks—and even months, accounting for resubmissions—for medically necessary services and items under the PA demonstrations. Moreover, GAO found that providers and suppliers may spend three to seven weeks obtaining the necessary documentation before submitting a PA request to a MAC for processing, which obviously further delays patients' care. We are particularly concerned that some MACs may not be honoring expedited PA requests, as described by

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<sup>1</sup> Survey summary available at <https://www.ama-assn.org/sites/default/files/media-browser/public/arc/prior-auth-2017.pdf>.

<sup>2</sup> These and other stories are available on the AMA's grassroots website <https://fixpriorauth.org>.

Mathematica in another recent report specifically evaluating the non-emergent hyperbaric oxygen demonstration.<sup>3</sup>

The waiting times characteristic of the CMS demonstrations far exceed the PA timeliness specifications outlined in a set of 21 best-practice Prior Authorization and Utilization Management Reform Principles endorsed by over 100 organizations representing physicians, medical groups, hospitals, pharmacists, and patients.<sup>4</sup> As stated in the principles, the reform coalition believes that health plans should provide PA decisions within 48 hours of receiving all required documentation, and urgent requests should be processed within 24 hours.

### **Administrative Burdens Associated With PA**

In addition to the impact of PA on patients, the AMA also underscores the significant administrative burdens and waste associated with utilization management programs. Our 2017 survey shows that practices complete an average of 29.1 PA requests per physician per week, and this PA workload consumes **14.6 hours—nearly two business days—per week of physician and staff time**. An overwhelming majority (84 percent) of physicians characterized PA-related burdens as high or extremely high. Moreover, PA hassles have been growing over time, with 86 percent of physicians reporting that PA burdens have increased over the past five years.

As with all PA programs, the CMS demonstrations have diverted practice time and resources away from direct patient care. Providers and suppliers interviewed for the GAO report indicate that the demonstrations' documentation requirements are difficult to fulfill. In fact, GAO notes that interviewed providers, suppliers, and CMS officials all stated that CMS PA documentation specifications are more challenging than those of commercial payers due to additional requirements, such as the need for physician signatures. In the Mathematica report on the hyperbaric oxygen demonstration, 93.8 percent of surveyed facilities indicated that PA requirements for this service had increased staff time spent on administrative duties. **Expanding the services that require PA under fee-for-service Medicare would substantially increase the PA workload that is already overwhelming physicians and their staff, as well as pull clinicians away from interactions with Medicare beneficiaries.**

CMS should also consider the increased administrative costs of expanding the PA program: GAO reports that the four demonstrations, which were limited to a small subset of states and services/items, resulted in over 337,000 PA requests over a period of less than five years. Continuing and broadening CMS' PA requirements would presumably consume significant MAC resources and result in increased administrative costs. The inefficiencies and administrative burdens involved in extending PA to additional Medicare-covered services conflict with the stated goals of the Patients Over Paperwork initiative.

### **Other Potential Reasons for the Cost Savings Reported by GAO**

The AMA reiterates our belief that the GAO report understates the impact of the PA demonstrations on both patients' access to timely, quality care and the administrative workload of health care professionals

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<sup>3</sup> Asher A, Contreary K, Haile G, et al. Interim Report for the Evaluation of Medicare Prior Authorization Model for Non-emergent Hyperbaric Oxygen. HHSM-500-2014-00034. Mathematica Policy Research: June 2018. Available at: <https://innovation.cms.gov/Files/reports/interimevalrpt-mpa-hbo.pdf>.

<sup>4</sup> Available at <https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf>.

to instead narrowly focus only on the potential cost savings. We urge CMS to factor in the potential for patient harms, additional medical expenses resulting from the adverse effects of PA-related care delays, and administrative costs for both providers and MACs in evaluating the future of PA in the Medicare fee-for-service program.

However, beyond our objection to the GAO's singular emphasis on cost, we note that CMS program activities that were instituted concurrently with the PA demonstrations may have contributed to the reduced expenditures on the applicable services/items reported by the GAO. For example, CMS began revalidating providers' and suppliers' enrollment in Medicare and implemented moratoria on enrollment of new providers for home health services and repetitive, scheduled non-emergency ambulance transport in select counties. These efforts may have prevented fraudulent providers and suppliers from billing Medicare and thus could have played a role in the reduced costs that GAO attributes to the PA demonstrations. CMS also instituted pricing and payment changes, such as competitive bidding and elimination of the lump sum purchase option for standard power wheelchairs, that could have reduced the expenditures on the items covered by the demonstrations. Finally, both CMS and MACs provide ongoing education and outreach to providers and suppliers regarding correct billing and Medicare coverage and payment requirements, which could have significantly contributed to the decreased costs reported by GAO. **We encourage CMS to consider these confounding factors when reviewing the estimated cost savings that GAO ascribes to the PA demonstrations.**

#### **Industry Consensus on the Need for PA Reform**

The AMA believes that the GAO's recommendations are not in alignment with a growing recognition across health care stakeholder groups of the critical need for reform in PA programs. The Prior Authorization and Utilization Management Reform Principles developed by the AMA and its coalition partners have spurred productive conversations between health care professionals and health plans about improving PA processes to reduce care delays and administrative burdens. Notably, the AMA, American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association released the Consensus Statement on Improving the Prior Authorization Process in January 2018.<sup>5</sup> This document reflects agreement between health care professionals and health plans on the need to reform PA programs through selective application of PA requirements to only outlier providers, regular review and adjustment of the services and drugs requiring PA, improved transparency and communication, protections for continuity of care, and automation to improve efficiency and transparency. **We highlight the fact that two of the focus areas outlined in the consensus statement—selective application of PA requirements and regular review of PA lists—address reducing the overall volume of services and drugs subject to PA.** In the context of this agreement to prioritize a broad reduction in PA volume, GAO's suggestion that CMS expand its PA program is out of step with the health care industry's current collective thinking on this issue.

We recognize that CMS has invested significant time and resources in reducing the manual burdens associated with PA through pursuing various technology options, including participation in the nascent Da Vinci project. We commend CMS for investing in PA automation to reduce health care professionals' administrative hassles, as technology plays a key role in the efforts to increase PA process efficiency.

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<sup>5</sup> Available at <https://www.ama-assn.org/sites/default/files/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

**However, we stress that automation should not be the only PA reform targeted by CMS, and that electronic processes are not a complete solution to the care delays and practice hassles associated with PA programs.** As detailed in the consensus statement, an overall reduction in PA volume, enhanced transparency, and protections for care continuity are also critical components of efforts to improve PA.

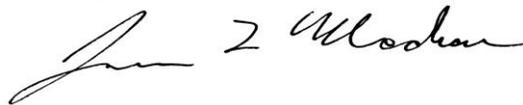
#### **Alternative Approaches to Program Integrity**

We recognize CMS' responsibility to serve as a steward of Medicare resources and ensure that program dollars are spent on legitimate, medically necessary care. However, given the significant negative impact of PA requirements on both patients and health care professionals, **we urge CMS to pursue alternative approaches to ensuring appropriate utilization of Medicare-covered services.** For example, and as reported by GAO, CMS has also engaged in ongoing educational efforts to support correct billing and adherence to Medicare coverage and payment requirements, and we strongly encourage CMS to continue these worthwhile activities. As noted by CMS staff interviewed for the Mathematica report on the hyperbaric oxygen demonstration, strategies other than PA that account for physician burdens and patient needs could achieve similar or even greater savings for the Medicare program.

#### **Conclusion**

The AMA shares your goal of providing the highest quality, most efficient care to Medicare beneficiaries. We enthusiastically support CMS in its efforts to reduce administrative burdens and maximize patients' time with their physicians. However, we firmly believe that the recommendations put forth in the GAO's report on PA run counter to these goals and priorities and are confident that we can collaborate with CMS to find alternative ways to ensure quality, high-value care for Medicare patients. **We strongly urge CMS to refrain from expanding Medicare PA programs or demonstrations before carefully considering the evidence that PA harms patients and burdens health care professionals.**

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD