March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
P.O. Box 8016
Baltimore, MD 21244-8016

> **RE: Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges**

Dear Administrator Brooks-LaSure,

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS)[1], I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the Notice of Proposed Rule Making (NPRM) outlining proposals to advance interoperability and improve prior authorization (PA) in Medicare Advantage (MA) plans, state Medicaid agencies and Medicaid managed care plans, Children's Health Insurance Program (CHIP) agencies and CHIP managed care entities, and issuers of Qualified Health Plans (QHPs) on the Federally-Facilitated Exchanges (FFEs) published in the *Federal Register* on December 13, 2022 (87 Fed. Reg. 76238).

The AAO-HNS applauds CMS for acknowledging our concerns, as well as those of our patients, in this NPRM. Physicians in the United States complete an average of 41 PA requests every week, taking an average of 13 hours to process.[2] PA is one of the most time-consuming and expensive administrative requirements preventing physicians from spending more time with patients. Over

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[1] The AAO-HNS is the nation's largest medical organization representing specialists who treat the ear, nose, throat, and related structure of the head and neck. The Academy represents approximately 10,000 otolaryngologist-head and neck surgeons practicing in the United States who diagnose and treat disorders of those areas.
[2] 2022 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

90% of clinicians reported that PA requirements have a negative impact on patient clinical outcomes[3].

Burdens associated with PA are often cited as a top concern among Academy members. We appreciate CMS' attention, through rulemaking and multiple meetings with stakeholders like the AAO-HNS, to addressing the growing burden associated with prior authorization (PA) faced by both patients and providers. Thank you for your outreach to the provider community. We are solidly behind your goal of reducing administrative burdens for physicians so they can devote more time to patient care.

As CMS notes, "[every] reader of this proposed rule is a patient and has received, or will receive, medical care at some point in their life," and we commend CMS for the patient-centric focus of this rule. Specifically, we appreciate several meaningful proposals addressing significant PA reforms. As commented in greater detail below, the policy changes outlined in the proposed rule will significantly improve PA in MA and other impacted programs. **We thank CMS for recognizing the burdens associated with PA programs and urge you to adopt these policies as written, or with the strengthening recommendations detailed below, to support judicious, transparent, and clinically appropriate use of PA that protects patients' access to treatment.**

Our comments will address the following components of the rule: timely delivery of care; use of a single prior authorization process; MIPS reporting on use of e-PA; compliance enforcement; functional interoperability among all providers; and gold-carding programs for prior authorization.

I.   Timely Delivery of Care

CMS is proposing that beginning January 1, 2026, "impacted payers would be required to provide a specific reason for denied prior authorization decisions, excluding prior authorization decisions for drugs, regardless of the method used to send the prior authorization request." CMS is also proposing that "responses about a prior authorization decision sent through the PARDD API from the payer to the provider would have to include information regarding whether the payer approves (and for how long) or denies the prior authorization request, or requests more information from the provider to support the request." Payers impacted by these proposals include "MA organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs." The Academy strongly supports these proposals. Taken

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[3] Id.

together, they represent a significant reduction of time and effort on the part of providers and staff. Finalizing these proposals as written would aid in transparency and allow providers and staff to address the reason for denial, re-submit, and advance the patient's treatment as quickly as possible. As patients gain increased access to a broader range of their health information, providers may similarly experience a larger volume of inquiries about the status of prior authorizations and other information requests. **We urge CMS to consider the evolving nature and volume of patient inquiries and adapt its regulatory policies to take those demands into account.**

In the rule, CMS proposes to shorten prior authorization timeframes to no later than seven days for standard requests, and 72 hours for expedited requests. The Academy concurs that maximum response timeframes must be implemented. However, we believe that given the adoption of electronic submission processes and specialty-peer clinical review, these timeframes can be shortened. For patients to receive the care they need with minimal delay, the quicker the response, the better the clinical outcome. Thus, we urge CMS to require impacted payers to respond within 72 hours for standard requests, and 48 hours for expedited/urgent requests.

We echo the comments made by the Alliance of Specialty Medicine, a coalition of which the AAO-HNS is a member, stating the importance of peer review of prior authorization requests by clinicians in the same specialty and sub-specialty as the ordering provider. This ensures that decisions as to medical necessity are made accurately with the requisite specialty knowledge involved. When a physician receives prior authorization for a service, they should be paid for that service. Our members have reported instances where payers have denied payment after the service has been approved. This practice disregards clinical evidence and adds to administrative burden. To improve the prior authorization process in a holistic manner, we believe it is important that CMS finalize the policies in this rule in conjunction with the prior proposed rule regarding the use of prior authorization in the Medicare Advantage program.

II. Single Prior Authorization Process

The AAO-HNS opposes CMS' decision to exclude drugs from the items and services subject to the proposed Patient Access API requirements impacting PA. The Academy urges CMS to extend the proposed prior authorization policies and payer requirements to drugs, including in-office drugs. CMS

clearly states that only prior authorization for items and services are within the scope of this proposed rule. However, medications are an essential component of patient care. Providers should be able to gain approval for prescribing the necessary drugs for a patient's treatment through similarly streamlined processes and evidence-based practices as the other components of their treatment plan.

While we understand that there already may be processes in place for electronic prior authorization for retail Part D drugs, these do not apply to Part B drugs administered in-office. To maximize the reduction in provider burden and improve care and outcomes for our patients, we urge CMS to reconsider how drugs are materially different than items and services and instead require a single process for all prior authorization requests.

Additionally, we strongly oppose using prior authorization in Medicare Fee-For-Service, and request CMS suspend existing FFS prior authorization policies rather than attempt to extend the proposals in this rule to FFS. The Academy concurs with concerns from Congress and the Medicare Payment Advisory Commission that extending prior authorization into FFS could adversely impact patient access to care and health outcomes.

III.   MIPS Reporting on Use of e-PA

To incentivize providers' use of electronic prior authorization solutions, CMS proposes adding a new measure titled "Electronic Prior Authorization" in the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category. **The Academy opposes the idea of including a MIPS measure on physician use of e-Prior Authorization (e-PA), even one which is non-weighted or voluntary, for a number of reasons.** The proposed measure — which clinicians would be required to report beginning in 2026 — would evaluate how often a clinician requests prior authorizations electronically. Importantly, this measure would only apply to a minority of our members who are not employed by a hospital or in an academic setting. The measure would not be scored initially, but clinicians would be required to report a numerator and denominator to identify the percentage of prior authorizations requested electronically from a PARDD API using data from certified EHR technology (CEHRT). However, the Academy believes it would be impossible to track the difference between insurance companies' response to PA requests to determine the numerator or denominator for this measure.

The application of broad and disparate PA policies leads to providers navigating disparate payer prior authorization processes and systems, waiting for decision responses, and appealing clinically inaccurate decisions. Provider use of prior

authorization in and of itself is not the problem. This proposed rule aims to reduce provider burden while improving patient access to care. Adding another item for physicians to measure and report on would be counterproductive. Furthermore, there is no federal health IT certification criteria in place, so it is unclear how the EHRs would communicate with payers' PARDD APIs, and thus how this measure would be reported accurately and fairly.

IV.   Compliance Enforcement

The Academy believes that clear enforcement mechanisms are key to successful adoption of a single, electronic prior authorization process, and the associated patient and provider benefits that such a process entails. **We request CMS provide a clear outline of current enforcement regulations that impact affected payers and identify the regulatory gaps that must be closed to ensure compliance with the proposed requirements.**

Additionally, CMS states that a great deal of enforcement would fall to the provider. The proposed rule indicates that "if a payer fails to meet the timeline of approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision." This is not dissimilar to the current environment, which relies on provider-led compliance enforcement and is not functioning efficiently. The proposal as outlined continues to put the onus of enforcement on the provider. This is contrary to the stated intent of the rule and does not guarantee that enforcement would be effective or lead to corrective action on the part of payers in any way.

V.   Functional Interoperability Among Providers

The 21st Century Cures Act Information Blocking rule generally describes practices that could be considered "information blocking" by different entities and actors in the healthcare environment. The purpose of the law, as drafted, is to ensure that a patient's data can be exchanged, when necessary, among entities involved in their care, to better coordinate care and yield improved health outcomes. However, the Rule does not include health plans and payers, so it's unclear if those entities would be obligated to adhere to the policies contained therein. Effective exchange of health data is critical to patient outcomes, and health plans and payers are involved in the exchange of that data. We request that CMS clarify the Information Blocking compliance obligations of health plans and payers.

The Academy supports the three interoperability proposals laid out in the "Advancing Interoperability" section. When taken together, these provisions would facilitate the effective exchange of health data necessary to patient care among the key actors involved, leading to improved health outcomes. We find particular value in the proposal to add a Provider Access API, that includes prior authorization requests and decisions in the categories of data that must be made available, and the requirement that all APIs adhere to a generally consistent set of standards aligned with the standards adopted by the Office of the National Coordinator for Health IT (ONC).

We believe that CMS should track potential unintended consequences of the requirement that payers make claim and encounter data available through standardized FHIR APIs within one business day after a request. We value the ability of patients and providers to quickly access necessary health data. However, we are concerned that payers might put undue pressure on providers to accelerate the submission of this data solely to comply with these API requirements. We therefore request that CMS institute regular check-ins with patient and provider groups to understand the real-world impact of this requirement.

The proposed rule would require payers to share data only with providers in their network. CMS should extend this requirement to include all providers, assuming they can verify their relationship to the patient. Patients do not only seek care within their payer network, and to maximize health outcomes, care must be coordinated among all providers involved in the care continuum.

We support the intent of the Payer-to-Payer API. For patients covered by multiple payers, it is important that each entity involved be able to exchange data to facilitate and support optimal coordination of care. This represents a great potential savings of provider time and resources. To maximize the benefit of the Payer-to-Payer API, we support an additional requirement that payers honor prior authorization approvals from prior payers, such as in the case of a job change and related insurance coverage shifts which occur during an episode of care. If the treatment has already been deemed clinically necessary, that decision should be maintained.

VI.   Gold-carding Programs for Prior Authorization

Through the NPRM, the agency asserts its intention to consider the implementation of gold-carding requirements through future rulemaking. **The AAO-HNS strongly supports the use of these programs, which would**

exempt physicians with track records of high approval rates from a health plan's PA requirements. In states such as Texas, gold-carding programs have proven to alleviate unnecessary and duplicative administrative burdens and help to facilitate more efficient, high-quality care. We also support CMS' suggestion to add a gold-carding measure in quality star programs for MA plans and QHPs to drive payer implementation of these programs that will reduce physicians' administrative workload and minimize patient care delays. Finally, we support CMS' proposal to study the impact of gold-carding programs on diverse patient populations.

We support the agency's proposed multi-pronged approach around PARDD API compliance: adoption of standards, providing guidelines for Implementation Guides for standard development, and generally offering flexibility for developers and vendors.

VII. Conclusion

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide comment and recommendations regarding these important policies on behalf of our members. If you have any questions or require further information, please contact Maura Farrell, Senior Director, Advocacy at mfarrell@entnet.org or 703-535-3729.

Sincerely,

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