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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,

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

AAAAI greatly appreciates CMS' commitment and tenacity toward addressing the administrative challenges physician practices face with utilization management, including prior authorizations. The proposals offered through this rulemaking, and in the recently released *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs* proposed rule (CMS-4201-P), are poised to reduce provider burden, increase transparency, and improve care coordination. Taken together, these policies, if finalized, will significantly improve quality and patient outcomes. ***We urge CMS to consider the below recommendations for improving these proposals, and to accelerate implementation of these requirements as soon as possible.***

Proposals for Advancing Interoperability

Patient Access API

AAAAI appreciates and supports CMS' proposal to require that impacted payers make information about prior authorization requests and decisions (including related administrative and clinical documentation) for items and services (excluding drugs) available to patients no later than 1 business day after the payer receives the prior authorization

request or there is another type of status change for the prior authorization, as well as through the Patient Access Application Programming Interface (API). We are, however, deeply disappointed that CMS proposes to exclude drugs from these policies. Treatment and management of A/I conditions frequently relies on medications administered in the office or dispensed by a pharmacy. Excluding these medications is inappropriate. ***We urge the agency to include medications as part of the Patient Access API requirements.***

Provider Access API

AAAAI appreciates and supports CMS' proposal to require impacted payers to implement and maintain a FHIR API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient. However, ***we urge CMS to expand this requirement to include all providers, regardless of their network status, where they can verify a relationship with the patient.***

As this Agency is aware, many physicians – particularly those in specialty medicine – face extreme difficulty with network participation as many impacted payers (e.g., Medicare Advantage, Exchange plans) have adopted “narrow networks,” forcing many patients to seek care – especially specialized care – from out-of-network (OON) providers. Until CMS modifies the criteria on which network adequacy is based, OON providers should be able to access individual patient information through the Provider Access API.

Finally, and consistent with the above, ***we urge CMS to include medications as part of the Provider Access API.***

Payer-to-Payer Data Exchange on FHIR

AAAAI appreciates and supports CMS' proposal to require impacted payers to implement and maintain a Payer-to-Payer data exchange that would exchange the same set of data that is being proposed for the Provider Access API, including prior authorization data, with other payers when a patient has concurrent payers or changes payers. Foremost, ***we urge CMS to include drugs as part of this requirement, as for the reasons outlined elsewhere in this letter.***

In addition, we are disappointed that CMS is not proposing to require payers to review, consider, or honor active prior authorization decisions of a patient's former payer. Again, our patients rely on medications that are frequently subject to prior authorizations and other utilization management tactics, such as step therapy. If the basis on which utilization management decisions are made is clinically driven and evidence-based, then approvals should transcend across all payers without concern. For this reason, ***we urge CMS to modify its policy such that prior authorization approvals granted for a patient by one insurer would be honored for that patient by the next insurer.*** Further, while we oppose step therapy as a utilization management tactic, at a minimum, ***CMS should require payers to except patients from step therapy protocols that have been previously met under a prior plan.***

Proposals for Improving Prior Authorization Practices

Proposed Requirement for Payers: Implement an API for Prior Authorization Requirements, Documentation, and Decision

AAAAI appreciates and supports CMS proposal to require, by January 1, 2026, all impacted payers to implement and maintain a FHIR Prior Authorization Requirements, Documentation, and Decision API

(PARDD API). The PARDD API would 1) automate the process and allow practices to determine whether a prior authorization is required for an item or service, 2) make any documentation requirements available within the provider's workflow and support the automated compilation of that information from the provider's system, and 3) support an automated approach to compiling the necessary data elements to populate the HIPAA-compliant prior authorization transactions and enable payers to compile specific responses regarding the status of the prior authorization, including information about the reason for a denial. **We urge CMS to implement this requirement in totality and without limitations on the services that would be subject to the requirement.** As noted elsewhere in this rule, **we also urge CMS to include medications, including outpatient drugs, as part of this requirement.** Finally, **we urge CMS to work with its federal agency partners to ensure the PARDD API is included in relevant certification criteria for health information technologies (HIT).**

Requirement for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations

We fully agree that prior authorization processes could be improved through better communication between payers and providers. As such, AAAAI supports and appreciates CMS' proposal to require that impacted payers send information to providers regarding the specific reason for denial when a prior authorization request is denied, regardless of the mechanism used to submit the prior authorization request. As noted elsewhere in this rule, **we urge CMS to include medications, including outpatient drugs, as part of this requirement and to finalize the revised requirement.**

Requirements for Prior Authorization Decision Timeframes and Communications

AAAAI appreciates the intent behind CMS' proposal that impacted payers must provide notice of prior authorization decisions no later than seven calendar days for "standard" requests and no later than 72 hours for "expedited" requests, but are concerned these timeframes are too long and will negatively impact patient outcomes. **We urge CMS to revise the proposed timeframes so that standard requests are responded to within 48 hours and expedited requests are responded to within 24 hours, at a minimum. In addition, CMS should work with payers to further support patient care by requiring requests to be responded to in real-time, in the future.**

Public Reporting of Prior Authorization Metrics

AAAAI supports and appreciates CMS' proposal to, by March 31, 2026, require impacted payers to annually report certain aggregated prior authorization metrics from the previous year, including:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved, denied, and approved after appeal, with each metric aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved and denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer for standard and expedited prior authorizations, aggregated for all items and services.

We urge CMS to also require impacted payers to publicly report their top reasons for denials, which could help providers avoid common mistakes and assist CMS with improving these requirements in

future years. All of these metrics should be reported by service code, or at a minimum, by category (e.g., laboratory services).

“Gold-Carding” Programs for Prior Authorization

AAAAI appreciates CMS’ request for feedback on the possibility of future rulemaking on gold-carding programs to improve prior authorizations. **We support making gold-carding programs a requirement for impacted payers, as well as establishing Quality Rating System (QRS) measures that would link these to plan performance and, in some cases, financial incentives.**

Electronic Prior Authorization for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category

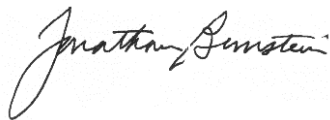
AAAAI strongly opposes CMS’ proposal to a new measure titled “Electronic Prior Authorization” in the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category. Such a measure would create undue administrative burden on physicians and contradicts the goals of this rulemaking. We also noted that there is no HIT certification criteria to support prior authorization in such technologies. Perhaps most importantly, such a measure could not meaningfully measure physician quality of care and patient outcomes, thus it would be inappropriate to hold physicians to such a measure. Finally, physicians have been clamoring for improvements in prior authorization processes, including automation through electronic means, thus the concern they would not use electronic prior authorization tools – where they are available and working appropriate – is irrational.

Other issues

CMS does not propose any enforcement mechanisms for impacted payers that do not meet the aforementioned requirements. As such, there is a strong likelihood impacted payers will not comply, which is deeply concerning. CMS must hold plans accountable for meeting these requirements. As such, **When impacted plans fail to comply with the requirements herein, AAAAI urges CMS to impose financial penalties, and in egregious cases, suspend or bar participation from Medicare Advantage, Medicaid Managed Care, or the Exchanges.**

We appreciate the opportunity to provide our perspectives on the aforementioned proposed rule. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@AAAAI.org or (414) 272-6071.

Sincerely,



Jonathan A. Bernstein, MD FAAAAI
President, American Academy of Allergy, Asthma & Immunology