March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: File Code CMS–0057–P. Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program**

Dear Administrator Brooks-LaSure:

The Advocacy Council of the American College of Allergy, Asthma and Immunology ("ACAAI") together with its sponsoring organization, the ACAAI, appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS's") *Advancing Interoperability and Improving Prior Authorization Processes* proposed rule published in the *Federal Register* on December 13, 2022 ("Proposed Rule").[1] The Advocacy Council and the ACAAI represent the interests of more than 6,000 allergists/immunologists and allied health professionals. ACAAI's members provide patient services across a variety of settings, ranging from small or solo physician offices to large academic medical centers. We respectfully submit the following comments in response to the Proposed Rule to advance interoperability and ensure that patients have timely and appropriate access to allergy services.

## Improving Prior Authorization Practices

Many treatments for allergies and asthma are subject to prior authorization requirements. The Advocacy Council and ACAAI strongly support all proposals that serve the goal of improving

[1] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act, Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program, 87 Fed. Reg. 76,238 (Dec. 13, 2022).

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prior authorization practices in terms of efficiency, the scope of accessible information, and the specificity of available information. Prior authorization procedures across health plans should be standardized to make the process less burdensome for payers, providers, and patients alike.

## I. Proposed Timeline for Determinations

The Advocacy Council and ACAAI urges CMS to implement proposals that require payers to respond to prior authorization requests within a specified timeframe. CMS proposes that impacted payers must provide notice of prior authorization decisions as "expeditiously as the enrollee's health condition requires," provided that a decision must be rendered no later than seven days for standard requests and no later than 72 hours for expedited requests.

It is critical that prior authorization processes do not inappropriately delay patient care. To that end, the Advocacy Council and ACAAI encourage CMS to reconsider its proposed timeline for prior authorizations. Rather than seven days for standard requests and 72 hours for urgent requests, CMS should reduce these deadlines to 48 hours and 24 hours, respectively. This recommendation aligns with CMS's goal to streamline the exchange of information. In addition, we recommend that CMS explicitly allow providers to treat a payer's failure to respond to a prior authorization request within the prescribed timeline as an approval of the prior authorization.

Lastly, we recommend that payers state in all denial letters the reviewer's "expertise" for a given service at issue. We strongly believe that the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested before the payer issues an adverse decision.

## II. Specific Reason for Denial

We encourage CMS to implement proposals that require payers to provide a specific reason for denying a prior authorization request. The Advocacy Council and ACAAI believe that denials generally citing "medically unnecessary" or "lack of documentation" are unhelpful to providers and patients. Therefore, we recommend that CMS establish standards that require payers to provide more specificity when explaining their reasons for denial. We also encourage CMS to require payers to communicate with providers in real time regarding the completion status of their prior authorization request.

## III. "Gold-Carding" Programs

The Advocacy Council and ACAAI believe that CMS should implement measures to reduce the volume of prior authorization requests that health plans are issuing. Exemptions should be in place for providers who get a majority of their prior authorization requests approved for specific services. We strongly support the agency's proposal to include a gold carding measure as a factor in Medicare Advantage organizations' and qualified health plans' quality ratings. This would serve as an important mechanism for these entities to raise their quality star ratings. Likewise, the Advocacy Council and ACAAI support CMS' proposal to require gold-carding as a requirement in payer prior authorization policies. However, we urge CMS to adopt necessary guardrails to ensure that payers do not circumvent this concept by preventing clinicians who

prescribe higher-cost biologics from reaching the threshold needed to achieve the gold card status. CMS should conduct appropriate oversight over gold carding programs.

## IV. Publicly Available Data

CMS' proposal that would require payers to make available a public report detailing information on denials, approvals, and appeals would serve as an effective mechanism to expand the specificity and scope of accessible information. The Advocacy Council and ACAAI recommend that CMS stratify this data by settings of care, items and services.

We also strongly support the Proposed Rule's requirements for the reporting of aggregated prior authorization metrics. These metrics include information regarding services that require prior authorization, the median and average processing time associated with making a determination, the percentage of both standard and expedited prior authorization requests that were either denied or approved, and the percentage of denials that were appealed (along with the success rate of approval upon appeal). We believe that this proposal would improve the level of transparency associated with the prior authorization process.

## V. Implementation of Prior Authorization Requirements, Documentation, and Decision ("PARDD") Application Programming Interface ("API")

CMS should implement its proposal to require payers, beginning January 1, 2026, to implement the Fast Healthcare Interoperability Resources ("FHIR") PARDD API. We support the proposal to make available through this technology a comprehensive list of covered services and items, links to forms or medical documentation that the payer requires for the prior authorization process, and any other necessary forms. We believe that a standard-based API such as this will increase efficiency in the prior authorization process. Additionally, the Advocacy Council and ACAAI maintain the position that attempts to implement APIs on a piecemeal basis will exacerbate confusion among the provider community. This is especially true given that there will likely be significant variation among payers regarding plans for implementation. Thus, the Advocacy Council and ACAAI support a uniform January 1, 2026 implementation date.

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

We do not support the agency's proposal to link prior authorization to the Promoting Interoperability performance category of MIPS. We are concerned that this would unnecessarily increase provider burden.

## VII. Application to Medicare Fee-for-Service ("FFS")

The Advocacy Council and ACAAI strongly oppose the idea of expanding prior authorization in Medicare FFS. We believe that expanding prior authorization in Medicare FFS has the potential to lead to limitations on patient access to care. Payers have increasingly employed prior authorization to inappropriately reduce costs and deny care. For instance, government reports indicate that Medicare Advantage plans routinely overuse, and indeed, abuse utilization techniques such as prior authorization. The Department of Health and Human Services Office of

the Inspector General ("OIG") released a report in 2018 that detailed "widespread and persistent problems related to denials of care and payment in Medicare Advantage plans."[2] A second OIG report in 2022 found persistent problems with Medicare Advantage plans issuing inappropriate denials of service and payment, including denials of prior authorization requests that met Medicare coverage rules.[3]

A recent Kaiser Family Foundation report found that in 2021, Medicare Advantage plans received over 35 million prior authorization requests.[4] More than 2 million of these requests were fully or partially denied and yet, when appealed, the vast majority (more than 80%) of appeals were fully or partially overturned. Unfortunately, only 11% of initial denials were appealed, demonstrating not only the burden of appealing prior authorization denials but also indicating that many beneficiaries are likely seeing their care being inappropriately denied.

CMS is currently in the process of reining in the egregious practices of Medicare Advantage plans. At this time, it would be inappropriate for the agency to expand the use of prior authorization in Medicare FFS.

## VIII. Enforcement

The Advocacy Council and ACAAI appreciate the agency's commitment to prior authorization reform. We believe that many of the provisions of the Proposed Rule would significantly improve communication among payers, patients, and providers, ease provider burden, and ensure more timely patient access to care. However, we have concerns regarding the lack of clear enforcement mechanisms under the Proposed Rule. We recommend that CMS incorporate a set of mechanisms for enforcement under the finalized version of the rule.

## Advancing Interoperability

The Advocacy Council and ACAAI strongly support CMS' goal to promote interoperability. In particular, we support the proposal which would require payers to streamline and make readily accessible the data exchange between providers, patients, and payers through Provider Access API and Patient API respectively. We support CMS' proposal that payers disseminate a Provider Access API because we believe that such a tool will serve the purposes of improving coordination of care and maximizing efficiency in rendering services. This proposal, if implemented, would both relieve provider burden and reduce delays in care for patients. Physicians spend an unreasonable amount of time completing and submitting prior authorization requests. If prior authorization practices are streamlined, providers can reallocate

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[2] U.S. Department of Health and Human Services, Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denial; Report (OEI-09-16-00410) (Sept. 2018).

[3] U.S. Department of Health and Human Services, Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care; Report (OEI-09-18-00260) (Apr. 2022).

[4] J. Biniek & N. Sroczynski, *Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021*, Kaiser Family Foundation (Feb. 2, 2023), https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021.

the time traditionally spent on activities related to prior authorization requests to patient care, thus enhancing the quality of care that patients ultimately receive.

We applaud CMS's effort to enhance the exchange of important health information to patients and, thus, encourage CMS to implement accessibility standards for Patient API. We further support CMS' proposal which would equip patients with the ability to change enrollment through the Payer-to-Payer Information Exchange. We believe the information that these APIs are required to provide—including certain clinical data elements as described in the USCDI v.1, claims and encounter data, and information related to prior authorization requests and determinations—will support CMS' goal of interoperability.

Thank you for your consideration of our comments. If you have any questions, please contact Susan Grupe at suegrupe@acaai.org.

Sincerely,

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