March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-0057-P,
P.O. Box 8013
Baltimore, MD 21244-8013

Re: 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 (CHIP) 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 Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) Prior Authorization (PA) proposed rule, published in the Federal Register on December 13, 2022. PAI supports the stated goals and overall approach of this proposed rule, which represents a significant improvement to prior authorization processes for federally regulated health insurance programs. We offer detailed comments and recommendations below.

PAI is a not-for-profit organization established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs from nine state medical associations, representing over 160,000 physicians nationwide.[1]

[1] California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association.

Overview and Key PAI Recommendations

PAI commends CMS for leading the industry towards goals that stakeholders across the health care system have long advocated for: automating and streamlining prior authorization (PA) processes and establishing greater consistency for its use across payers. We recognize and appreciate that this proposed regulation reflects CMS' broader commitment to reforming prior authorization as evidenced in the annual Medicare Advantage & Part D proposed rule for 2024, which aims to ensure Medicare beneficiaries' access to medically necessary care. PAI urges CMS to move forward expeditiously to finalize these important regulations, which reflect many of the key policies in H.R. 3173, the Improving Seniors' Timely Access to Care Act of 2021, which passed the House of Representatives with overwhelming bipartisan support late last year. PAI joined over five hundred organizations representing patients and physicians in supporting that critically important legislation. Our comments below include several policy recommendations to better align this regulation with the bill's widely supporting legislative provisions.

By mandating that payers establish a FHIR Prior Authorization Requirements, Documentation and Decision (PARDD) API for electronic prior authorization processes, this regulation will help reduce administrative burden and expense for payers and providers alike—including physicians. Establishing a more consistent approach to PA *across* payers will help ease the burden associated with complying with payers' disparate and often inefficient processes that cause enormous administrative burden for physician practices and delays in care for patients. Importantly, the rule will incentivize physicians and other health care providers – as well as IT vendors - to adopt processes to interact more seamlessly with the payers' APIs for the benefit of patient care.

PAI commends CMS for the breadth of this proposed regulation's reach across key federally regulated managed care plans, including Medicare Advantage, Medicaid, CHIP and Qualified Health Plans on the Federally Facilitated Exchanges. We believe that this will spur adoption even more extensively across the industry, particularly among the nation's large health insurers that also participate in state regulated commercial insurance markets and as third-party administrators for self-insured ERISA plans.

This proposed rule promotes greater transparency and ease of information exchange that will greatly aid physicians and their patients. The rule's mandated use of PARDD APIs will offer key process improvements including transparency around which services require PAs; better information about documentation requirements to promote more complete initial PA requests; enhanced ability to track the status of PA requests and view existing PAs; and greater transparency about the grounds for PA determinations that impact clinical care.

PAI offers the following recommendations to further enhance the rule's impact through additional provisions to support adoption by physicians and strengthen the rule's transparency requirements, including requiring transparency around the specific clinical guidelines used in PA determinations. PAI also recommends additional reporting by payers on metrics that will inform efforts to further streamline and speed PA processes (e.g., through "real time" determinations where appropriate) and protect patients from unnecessary delays in care. This will also support monitoring and enforcement, which PAI views as an important component to ensuring compliance with these requirements.

Key Recommendations:

1. Require payers to disclose any clinical criteria used as the basis for medical necessity determinations during the prior authorization process and specifically identify the grounds for denying a prior authorization request. This information should be incorporated into the PARDD API and available upon request to physicians who are not yet able to submit PA requests through the API. In addition, CMS should further refine the requirement that payers identify with specificity the grounds for denying prior authorization requests to allow physicians and patients an opportunity to supplement a request with additional information and/or documentation and if necessary to appeal PA denials. It is also critical that CMS promote the use of a universal language for describing PA decisions and adopt operating rules for the 278 transactions as these will achieve the end goal of establishing consistent electronic descriptors for PA responses across payer APIs.

2. Require more detailed payer reporting on key PA-related metrics. Requiring payers to publicly disclose key PA-related data serves several important goals, including supporting process improvement and oversight and enforcement, by identifying outlier or problematic practices. In addition to the metrics identified in the proposed regulation, PAI recommends that CMS require payers to publicly report detailed statistics at a service/item-specific level. This reporting should be consistent with other clinical and administrative uses (by HCPCS codes, CPT®, and ICD-10).

3. Further shorten PA determination timelines and utilize payer-reported information to identify a list of items and services that warrant "real-time" determinations based on high approval rates. PAI supports shortened timelines for PA determinations. In addition, detailed reporting at the level identified above will support implementation of important additional PA policies to further streamline PA processes to benefit patients, including efforts to identify frequently approved items and services for which near "real time" determinations may be warranted and "gold carding" programs, which help streamline PA considerably for physicians whose PA requests are regularly approved.

4. Extend the proposed rule's provisions to "out-of-network" health care providers, including physicians. As plans offer increasingly "narrow" provider networks, patients are too often forced to seek treatments and services "out-of-network," which typically includes greater out of pocket costs to patients. Excluding out-of-network PA requests from the rule's electronic PA mandate would establish a two-tiered PA system and negatively impact these patients' care.

5. Promote widespread use of the process envisioned in the proposed regulation through a range of policies (or recommendations to other federal agencies) to help physicians fully integrate electronic PA into their practice workflow. PAI identifies a range of policies to support physicians' efforts, including direct financial support for investments in compliant IT platforms, allowing these physicians to access insurer APIs as they work towards full capability, and supporting flexible sources of documentation to support PA requests within the established framework.

6. Develop an oversight and enforcement process. This is needed to ensure compliance with the regulatory requirements and provide a process for patients and physicians to report noncompliant payers.

Provisions to Enhance Transparency

This proposed rule establishes important new standards to enhance, streamline and standardize processes to support automated prior authorization. The proposed rule requires payers to use an API process to directly share whether an authorization is required for a specific procedure, patient, or servicing physician in a specific contracted network. The API must also describe the specific patient information that the payer requires to support the decision process they use to determine medical necessity or benefits eligibility.

To better achieve these goals, the rule should also implement disclosure requirements to improve transparency around payers' coverage and medical necessity determinations. PAI recommends that CMS require payers to disclose through the PARDD API the medical criteria or guidelines used in PA determinations and provide specific information on the grounds for denying prior authorization.

Disclosure of Clinical Criteria Used in Prior Authorization Determinations

Payers commonly use medical necessity criteria and other clinical guidelines for prior authorization and other utilization review processes, which payers often deem proprietary and refuse to disclose to physicians or beneficiaries. Payers claim that this prevents health care providers from "gaming" the system by submitting documentation to ensure approvals for services are consistent with best medical practices. Conversely, PAI believes that this "black box" approach creates a system that allows payers to make medical necessity determinations that impact their beneficiaries' health without appropriate accountability, and in many cases, to maximize their own profits.

Without understanding the underlying criteria that payers apply to medical necessity determinations, physicians are left trying to anticipate what the payer may request as evidence of medical necessity or for authorization of a procedure or service. This has contributed to the inefficient, time-consuming and costly "back and forth" between physician practices and payers as physicians work to ensure that their recommended course of treatment for patients is covered by insurance.[2] While properly developed evidence-based medical guidelines are important to

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[2] Physicians have identified growing use of prior authorization by insurers as a significant barrier to providing timely and necessary care to their patients. A 2021 American Medical Association (AMA) survey of physicians on the impact of PA found that 93 percent of physicians reported delays in treating patients while waiting for insurers to authorize necessary care, and 82 percent said prior authorization led to the abandonment of treatment plans by patients because of prior authorization struggles with their insurance company.[2] Prior authorization not only jeopardizes access to care but also quality of care. In the same survey, 34 percent of physicians reported that PA had led to a serious adverse event for a patient in their care. The 2021 AMA prior authorization physician survey found that 24 percent of physicians reported that PA had led to a patient's hospitalization and 18 percent reported that PA had led to a life-threatening event or required intervention to prevent permanent impairment or damage.

In addition to undermining best clinical practices, the administrative inefficiencies associated with payers' increasingly widespread use of prior authorizations add significant and unnecessary costs to the health care system. CMS estimates that efficiencies introduced through policies in this proposed rule would save physician practices and hospitals over $15 billion in a 10-year period. Those findings are consistent with analysis related to the automation of a range of health care transactions, including PA. In 2019, the Council for Affordable Quality Healthcare (CAQH) concluded that the health care industry can save an estimated $13.3 billion annually on administrative spending through automation of eight transactions including PAs.[2] Other analyses and industry surveys point to higher potential savings for reforms to PA. Respected industry

promoting high quality, efficient care, physicians are also ethically obligated to treat each patient individually, using their best medical judgment after considering *all* relevant information. This additional transparency would in no way undermine payers' requirements that physicians submit appropriate, verifiable documentation to support their recommended course of treatment; it would simply enable them to do so more efficiently.

Furthermore, while PAI appreciates CMS' intentions to use the API process as a mechanism for transparency and promote more widespread adoption of electronic PA processes, there will be certain physicians who will remain unable to adopt these systems by the implementation date due to financial and operational barriers. PAI, therefore, recommends that plans should provide to each contracted physician, upon request and regardless of their use of the API, the references to the clinical research evidence that underlies medical policy determinations when they approve or deny a service.

Denial of Prior Authorization Decisions

The proposed rule requires payers 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.

PAI supports the requirement that payers provide clear information regarding the reason for PA denials and urges that CMS refine this further. Importantly, CMS should include a requirement that payers consider all submitted information and documentation tied to the PA request (e.g., for PAs that have multiple documentation requests). For payer PA determinations based on medical necessity or missing/inadequate supporting documentation, CMS should require payers to provide specific information explaining why an item or service was deemed medically unnecessary and/or what specific documentation would be needed to support the request. CMS should require payers share through the API a clearly defined process to allow physicians an opportunity to address the PA denial, regardless of the basis, including an expedited process for urgent patient medical care needs.

Finally, successful automation of the PA process depends on many technical considerations that ensure shared information is universally understood by industry participants. The approach CMS took mandating electronic funds transfer and remittance supports the value of clarity and uniformity in information exchange. In the case of PA, CMS can refer to a rule related to uniformity in coding—

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organizations (e.g., AMA, Workgroup for Electronic Data Exchange) estimate that the physician operating costs associated with PA are at least double this estimate. Costs for the PA process affect many parts of physician practice operations; CAQH captures the costs associated with a narrow band of the PA process, but it does not capture the end-to-end impact on practices.

According to the AMA, on average, practices must complete 41 PAs per physician each week.[2] This workload consumes almost two business days of physician and staff time, with 40 percent of physicians reporting that they have hired staff to work exclusively on PAs. Reforming prior authorization processes, including through automation, will reduce the amount of time physicians and their clinical and administrative staff spend on these administrative tasks, allowing more time to spend on direct patient care.

CAQH CORE Payment & Remittance Uniform Use of CARCs and RARCs Rule—as an example.[3] This rule brought uniformity to the use of certain codes—Claim Adjustment Reason Codes (CARCs) and Remittance Advice Remark Codes (RARCs)—by identifying a limited set of code combinations in universal business scenarios under the auspices of the Health Care Services Review Information specifications. CMS should adopt operating rules for the 278 transactions as these will achieve the end goal of establishing CARCs and RARCs for PA responses, which would ensure consistency across payer APIs.

Relatedly, we support the proposed rule's stated goal that an API should allow physicians and patients to check the status of prior authorizations throughout the PA process. However, PAI is concerned that the proposed rule does not allow for requirements for systems to include functions that allow for that back and forth "inquiry and update capability." To support this capability, PAI recommends that CMS provide technical guidance to payers regarding how current HIPAA 278 transaction requirements and other transaction code sets will work with FHIR based APIs.

Prior Authorization Reporting and Data Collection

The proposed regulation also requires that insurers report annually on a set of PA metrics. PAI believes that transparency around these PA metrics is critical to improving processes systemwide and assessing individual payers' prior authorization practices, which of course impact beneficiaries' access to medically needed care. As outlined below, requiring insurer reporting on more detailed PA metrics will better support regulatory oversight as well as future efforts to address problematic PA practices.

CMS proposes that payers must make the following data from the previous year publicly accessible, aggregated for all items and services:

- List of all items and services that require PA.
- Percentage of standard PA requests: approved/denied, approved after appeal, and where review was extended and request was approved
- Percent of expedited PA requests approved.
- Percent of expedited requests denied.
- Average and median time between submission of a request and determination by the plan, for standard PAs.
- Average and median time elapsed between submission of request and decision by plan for expedited PA.

Reporting Service/Code Specific PA Metrics - PAI recommends that CMS require that payers annually report on the various PA metrics by item or service (by HCPCS codes, CPT®, and ICD-10) as well as in the aggregate. This is consistent with the provision proposed in the Improving Seniors' Timely Access to Care Act, which requires data regarding approvals and denials to be disclosed by item or service and in the aggregate. This level of reporting is necessary to fully support additional efforts to streamline PA and provide greater insight into how PA processes impact patients who require specific medical treatments. CMS has a strong interest in collecting this data to support

[3] https://www.caqh.org/core/ongoing-maintenance-core-code-combinations

ongoing oversight and future policymaking, particularly around specific procedures and tests that should be exempt from PA and/or subject to a "real-time" determination standard.

Oversight/Enforcement **-** PAI recommends that CMS actively oversee implementation and compliance by affected payers. This should include reviewing insurers' reported PA metrics and establishing a process for addressing insurers that report unusually high PA denial rates or longer than required times between submission requests and determination. PAI also recommends a grievance process to allow patients and providers a mechanism for reporting noncompliant payers by service, procedure and medical condition.

"Gold-Carding" and Other Innovative PA Reforms – PAI recommends CMS collect detailed information on payers' frequently approved items and services as this would help the Agency support innovative programs to streamline prior authorization, including "gold carding" programs that reward physicians and other clinicians with high rates of PA approvals for certain services with relief from PA requirements because of demonstrated adherence to clinical quality care guidelines. We also encourage the inclusion of a gold-carding measure as a factor in quality ratings for Medicare Advantage organizations and Qualified Health Plans as a way for these payers to raise their scores in the quality star ratings. PAI is supportive of gold-carding and other innovative PA reforms as they improve patient care and reduce burnout among physicians.

Ensuring Timely Prior Authorization Decisions

The potentially devastating physical and emotional impact of prior authorization is often felt by patients who are delayed in getting their medication or treatment. Long wait times harm both patient experience and patient care, especially those requiring urgent determinations. Consistent with the goals of this regulation and the shift towards automated PA processes, PAI agrees that CMS should adopt much shorter timelines for determinations. CMS proposes to shorten the existing timeframe for plan determinations from 14 to 7 days for normal requests and requires payers to make urgent determinations within 72 hours.

PAI encourages CMS to shorten even further the existing timeframe for plan determinations for both normal and urgent requests. We further recommend that CMS institute a near real-time decision-making process for frequently approved items and services and establish a list of services that should not be subject to prior authorization.

Timelines for Standard and Expedited Decisions **-** While PAI appreciates CMS attempting to set shorter deadlines for payers to address prior authorization decisions, we believe that both timeframes are still too long by clinical standards. Notably, the Improving Seniors' Timely Access to Care Act included more timely PA determinations by Medicare Advantage plans. PAI urges CMS to consider aligning with the bill's provision and requiring payers to provide notice of PA decisions no later than 24 hours after receiving a request for expedited decisions and no later than 3 days for standard decisions.

Services Appropriate for "Real-Time" Adjudication **–** Utilizing the data gleaned from the enhanced (including PAI-recommended code-level) reporting requirements in the proposed rule, PAI urges

CMS to adopt a process to identify a set of services for which PA adjudication can occur in "real time" due to automation. These are services that require prior authorization approval (e.g., annual screening mammograms) but where denials are made based on eligibility or other coverage rules rather than for lack of medical necessity (i.e., the beneficiary's last screening was less than a year prior, and the plan only covers one per year). This recommendation is also consistent with the provision proposed in the Improving Seniors' Timely Access to Care Act, which requires the Secretary to create and update a system where it collects information from payers to determine a set of items and services eligible for "real time" decisions.

As payers adopt the processes required in this proposal, automated systems will be able to immediately determine if there are benefit or plan coverage issues for this subset of services. As such, there is no justification for allowing payers multiple days to approve or deny a PA request. Moving to "real time" adjudication for these services would further streamline PA processes and support improved clinical care in a manner consistent with this proposal.

To support this goal, CMS should create and update a system collecting information from payers to determine a set of items and services eligible for real time determinations.

Services That Should Not Be Subject to Prior Authorization - There are certain medical conditions that by their very nature need immediate attention, when even waiting for an expedited approval process would seriously threaten a patient's life or health. Examples of these services include emergency surgeries (e.g., surgery to correct a brain aneurysm, emergency C-section surgery, etc.). These services should be wholly exempt from mandatory prior authorization requirements. We again emphasize that CMS must collect detailed data regarding how payers treat (i.e., approve or reject) specific services/codes so that the agency has sufficient information to assess future policies, including where PA is not appropriate.

Retrospective Review to Deny Previously Approved Treatment - The proposed rule does not include any policies related to retrospective review after a prior authorization request is approved. PAI recommends that CMS adopt a policy to restrict the use of retrospective review to revoke previously approved services (through the PA process required in this proposal). Except in very rare instances where intentionally misleading information was provided during the prior authorization process, payers' use of retrospective review processes to revoke previously approved services are generally inappropriate, as it leaves the physician or other health care provider uncompensated for treatments approved by the payers utilizing their own criteria and processes. Absent evidence of fraud, it should not fall on the health care provider to shoulder the financial burden if an individual provides inaccurate information regarding his or her status as insured.

Physician Engagement in the Electronic PA Process

CMS proposes to require impacted payers to implement the PARDD API (i.e., HL7 FHIR) that would work in combination with the adopted HIPAA transaction standard to conduct the PA process by January 1, 2026. While PAI generally supports this provision, CMS excluded prior authorization requests from "out-of-network" health care providers, including physicians, from the policies established in the proposed rule. Plans often adopt limited or "narrow" provider networks as a cost-

containment strategy and a lack of rigorous network adequacy oversight has exacerbated this problem, particularly for patients with complex medical conditions who need specialty or sub-specialty care not available or readily accessible in-network. If payers are allowed to continue utilizing outdated PA processes for out-of-network services, they will have an even greater financial incentive to engage in contracting practices that result in more out-of-network care. Excluding prior authorization requests from out-of-network providers will result in a two-tiered PA process for patients who seek medical care outside of the plan's contracted provider network. This will further delay care for patients and result in the abandonment of treatment plans by patients due to growing mistrust of the health care system.

For these reasons, PAI urges CMS against excluding "out-of-network" prior authorization requests from the streamlined electronic PA processes set forth in the proposed rule.

Additionally, to promote adoption by physicians, CMS proposes to add a new measure related to the new PA process in the Health Information Exchange (HIE) objective of the MIPS performance category Promoting Interoperability and in the HIE objective of the Medicare Promoting Interoperability Program. CMS would require MIPS-eligible clinicians to report this measure—Electronic Prior Authorization— beginning with the calendar year (CY) 2026 performance period/CY 2028 MIPS payment year.[4] PAI supports this as one means of promoting physicians' use of the API for PA.

Additional policies to promote adoption of electronic PA processes by physicians include:

- As noted above, some physicians will continue to need flexibility in the tools they use to support efforts to utilize electronic PA. For instance, physicians should be allowed to use FHIR artifacts as an option for submitting clinical data inside the x12N 275 standard mandated for attachments (i.e., a standard approach that physicians must use to submit an electronic prior authorization request to a health plan). It is imperative that CMS ensures that physicians can use both FHIR-based and Consolidated Clinical Data Architecture (C-CDA) requests in those submissions to avoid the unnecessary cost and burden of translating FHIR requests to C-CDAs.
- To speed this adoption by smaller practices, especially those in very urban or rural locations, CMS should consider creating technical assistance programs to help them transition into using electronic PA.
- CMS should consider recommending direct financial incentives to encourage physicians to move toward the use of electronic PA, as many smaller practices may not have the financial resources to utilize the technology.
- Physicians should also continue to have the option to use the API while they develop full electronic PA capabilities. CMS should require payers to maintain a low cost/no cost portal access to the mandated workflow built on top of the API capabilities. This option allows physicians who are transitioning to APIs the ability to gain familiarity with electronic prior authorizations.
- CMS should establish a working group that includes representatives of physicians, other clinicians, hospitals and health insurers, as well as vendors, including claims clearinghouses

[4] https://www.healthit.gov/sites/default/files/page/2021-04/FHIR%20API%20Fact%20Sheet.pdf

and EMR companies, to both monitor and evaluate how the rule is functioning and if there are any universal issues or concerns that need to be addressed through additional regulation.

Standardizing Across Government Regulated Programs

One of the most problematic aspects of prior authorization for physician practices is that every payer has different procedures and policies, making it incredibly time-consuming and burdensome to navigate across multiple payers. Standardizing PA processes across payers has been a long-term goal for physician organizations to allow physicians to focus more of their time and energy on patient-centered care.

Program Application

CMS proposes that this rule will apply to Medicare Advantage organizations, state Medicaid FFS programs, state CHIP FFS programs, Medicaid managed care payers, CHIP managed care entities, and QHP issuers on the Federally facilitated exchange.

PAI supports CMS' proposed regulation that would adopt a standardized regulatory approach to PA that span government-regulated programs. Further, PAI recommends that CMS align prior authorization requirements for Medicare Advantage organizations in the Medicare Part C/D rule with this proposed regulation to ensure standardization of utilization management and continuity of care to protect patients from delay in treatment and disruption of care. With uniform prior authorization policies, physicians would be able to adhere to one set of rules for purposes of audits, oversight, and/or program integrity. It would also preclude the divergent interpretations and approaches that state Medicaid programs currently operate under. Without a greater degree of uniformity across payer modalities, patients and physicians will continue to face arbitrary administrative burdens inhibiting the efficient delivery of care.

Prescription Drugs

The proposed rule does not require impacted insurers to utilize the PAARD API to support prior authorization processes for prescription drugs.

PAI recommends that CMS require payers to utilize the PAARD API to support PA processes for prescription drugs. Additionally, CMS should update their Prior Authorization Requirements, Documentation and Decision (PARDD) processes and applicable medical service types to align with the HIPAA regulations associated with the 278. Policies should be consistent across all government-run programs.

Conclusion

Overall, PAI recognizes and appreciates the Agency's efforts to streamline prior authorization processes and reduce physician burden. Not only is prior authorization—in its current state—burdensome, unpredictable, and time-consuming for physicians, it also causes harmful delays in patients receiving the care they need. While PAI supports the key provisions in the proposed rule, we strongly urge CMS to expand upon its proposed policies and require further transparency and specificity from payers, expedite the timeliness of PA decisions, require quicker implementation of

the electronic PA process for payers, and standardize proposed policies across all government regulated programs.

If you have any questions, please contact me at k2strategiesllc@gmail.com.

Sincerely,

Kelly C. Kenney
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