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Submitted via regulations.gov

March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (CMS-0057-P)

Dear Administrator Brooks-LaSure:

On behalf of the Large Urology Group Practice Association (LUGPA), we appreciate the opportunity to comment on the above captioned Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule ("Proposed Rule"), which builds on the May 2020 CMS Interoperability and Patient Access Final Rule ("2020 Final Rule") and withdraws the December 2020 CMS Interoperability and Prior Authorization Proposed Rule ("2020 Proposed Rule"). LUGPA represents 150 urology group practices in the United States, with more than 2,100 physicians who, collectively, provide approximately 35% of the nation's urology services.

LUGPA supports CMS' proposals to require impacted payers[1] to implement the Application Program Interface (API) for prior authorization; establish timelines for impacted payers to issue prior authorization determinations; and apply these standards to Medicare Fee-for-Service (FFS).

Additionally, LUGPA respectfully requests that CMS set the implementation date for these provisions earlier than the proposed date of January 1, 2026. Finally, while LUGPA agrees with CMS that the current prior authorization processes require improvement to reduce burdens on providers, we respectfully request that CMS does not implement the proposed "Electronic Prior Authorization" measure under the Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category.

1. Defined as Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges

I. BACKGROUND ON LUGPA

The Large Urology Group Practice Association (LUGPA) was formed in 2008 to facilitate communication between independent urology-focused (GU) groups of ten or more providers. This served the complementary priorities of: (1) the promotion of clinical and operational benchmarking to guide best practices; (2) the establishment and promulgation of quality guidelines; and (3) the utilization of resources for advocacy and communication in the legislative and regulatory arena. LUGPA was thereby able to ensure that its providers had an opportunity to advocate on behalf of their patients and their specialty at a national level. Since that time, LUGPA has expanded its mission to incorporate any non-hospital-based group practice who shares the foundational principles of commitment to providing integrated and comprehensive GU services to those impacted by genitourinary diseases and conditions. LUGPA has gained membership steadily; it currently includes 150 urology group practices in the United States, representing more than 2,100 physicians who, collectively, provide over 35% of the nation's Medicare urology services.[2] Furthermore, LUGPA's members provide most of the GU care delivered in the independent physician office setting.

As health care reform efforts in the US have evolved to redirect focus towards the development and promotion of outcome driven, "best-practice" patient care delivered in the most cost-effective setting, LUGPA practices have consistently been leaders in innovative and adaptive care models. Expanding both the range of procedures and the integration of care that can be safely and effectively provided in the independent physician setting has resulted in improved access, demonstrable concomitant reduction in the cost of care delivery, as well as improved outcomes. In addition, LUGPA practices have been at the forefront of adopting team-based healthcare, with broad incorporation of other physician specialists and a variety of advanced practice providers, maximizing both convenience and accessibility to expert treatment for the full spectrum of GU conditions. LUGPA practices have embraced value-based care models, and the organization was among the first to create a physician-focused payment model. As such, LUGPA has continued to be a leader in the development of high-quality, cost-effective alternatives for care delivery as a counterbalance to the cost increases associated with the trend towards consolidation of health care services.

LUGPA's mission has been to promote and support access to the resources, technology, management tools and advocacy efforts that optimize the ability of independent practice urologists and their clinical partners to deliver effective and efficient care for patients with acute and chronic GU conditions. During the global Public Health Emergency (PHE), LUGPA's mission was expanded to provide crucial resources to independent physician practices so as to enable continuity of outpatient services, even as the nation's inpatient capacity was overrun by patients stricken with COVID-19. During this unprecedented crisis, LUGPA's team worked in Congress to advocate on behalf of all independent practice providers as emergency funding measures to sustain critical medical infrastructure were considered. We did so by assisting membership with guidance regarding the applicability of and access to government assistance programs subsequently, by

[2] Utilization numbers based on cross-referencing LUGPA membership data with 2020 Medicare Physician & Other Practitioners Public Use Files. Accessed at: https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners, January 1, 2023.

coordinating sourcing of personal protective equipment, and by providing crucial safety data to its members. Through these and other efforts, LUGPA helped ensure that vulnerable populations continued to be able to access life-saving urological services.

LUGPA will continue to work on behalf of its membership to ensure that the integral role of independent GU practices is recognized and optimized as we work to expand access to current and up-to-date treatment alternatives in the most cost-effective setting.

II. CMS SHOULD IMPLEMENT THE PRIOR AUTHORIZATION API REQUIREMENT IN A MANNER THAT DOES NOT IMPOSE FURTHER BURDENS ON PROVIDERS.

In the Proposed Rule, CMS seeks to alleviate burdens associated with the prior authorization process by proposing a requirement that all impacted payors implement and maintain a Fast Healthcare Interoperability Resource (FHIR) Prior Authorization Requirements, Documentation, and Decision (PARDD) API to be used by providers to facilitate the prior authorization process.[3] This API would mitigate some of the obstacles in the current prior authorization process by: (i) automating certain tasks for provider or office staff; (ii) allowing a provider to query the payor's system to determine whether prior authorization is needed and what kind of documentation is required for certain items or services; and (iii) supporting an automated approach for compiling the necessary data elements to populate the HIPAA-compliant prior authorization transactions and enabling payors to compile specific responses regarding prior authorization status, including the reason for a denial.[4] Additionally, CMS is proposing to require impacted payors to provide a specific reason for prior authorization denials, regardless of the method used to submit the request for prior authorization.[5]

LUGPA supports CMS' goal of streamlining the prior authorization process to reduce provider burden and allow providers to better focus on administering patient care, and we urge CMS to finalize the proposed requirements for impacted payors to implement PARDD API and to provide specific reasons for prior authorization denials. Notably, CMS in the Proposed Rule references the 2021 American Medical Association (AMA) provider survey[6], in which 82% of providers reported how prior authorization issues lead to treatment abandonment, and 93% of providers reported delays in care. CMS correctly notes that "[t]imely and clear information from payors about the status of a prior authorization or the reason(s) for denial could help mitigate these challenges and provide necessary information for submitting additional documentation or arranging for alternative treatment."[7] LUGPA appreciates CMS' recognition of the provider burdens associated with prior authorization, and how such burdens can impact patient care. **That said, LUGPA urges CMS to ensure this new PARDD API requirement is implemented in a manner that does not impose further burdens on providers.**

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[3] *Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule*, 87 Fed. Reg. 76238, at 76289 (Dec. 13, 2022).
[4] 87 Fed. Reg. 76238, at 76289.
[5] 87 Fed. Reg. 76238, at 76292.
[6] 2021 AMA prior authorization (PA) physician survey. Accessed at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf, March 7, 2023
[7] 87 Fed. Reg. 76238, at 76292.

Furthermore, LUGPA respectfully requests that CMS go further to limit the ability of impacted payors to impose unnecessary and excessively burdensome prior authorization documentation and process requirements. Although requiring payors to use a PARDD API is certainly a step towards streamlining the prior authorization process, it does not address the fact that some payors have implemented and imposed burdensome and unnecessary documentation, clinical criteria, and other requirements for prior authorization, which often lead to unnecessary delays in care and improper denials where care is in fact reasonable and necessary. This is compounded by what is often an onerous appeal process—this is much more difficult for specialty physicians as the payor representative is virtually never a subject matter expert and usually not a physician. Consequently, specialists spend considerable time explaining current clinical best practices to individuals who have no ability to evaluate the information as it relates to the requested action or service. As such, while LUGPA appreciates CMS's efforts to streamline the process with PARDD API, to fully "address prior authorization process challenges," CMS will also need to address the actual payor prior authorization processes themselves.

III. CMS Should Further Reduce the Timeframe for Payors to Provide Notice of 'Standard' and 'Expedited' Prior Authorization Decisions.

CMS also proposes to shorten timeframes and decisions on standard and expedited prior authorization requests, as part of its broader focus to improve health outcomes and ensure that patients can access services in a timely manner. Under the proposal, starting on January 1, 2026, MA organizations and applicable integrated plans, Medicaid FFS programs, and CHIP FFS programs would be required to provide notice of prior authorization decisions "as expeditiously as a patient's health condition requires," but no more than 7 calendar days for "standard requests."[8] Additionally, CMS proposes requiring that Medicaid FFS and CHIP FFS programs provide notice of prior authorization decisions no later than 72 hours for "expedited requests," unless a state law sets a shorter timeframe.[9] CMS also requests comments as to whether the proposed timeframes for MA organizations, applicable integrated plans, Medicaid FFS programs, CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities to provide notice of "standard" and "expedited" prior authorization decisions should be shortened even further, raising a 5-day timeframe for standard requests and a 48-hour timeframe for responding to expedited requests as examples.[10]

LUGPA appreciates CMS's efforts to expedite the prior authorization decision-making timeframe, and supports CMS's proposals to standardize and shorten delays in the process. Notably, CMS's proposal would shorten the timeframe for MA plans to decide on standard prior authorization requests from 14 to 7 days. However, LUGPA believes that a timeframe of 7 days for standard requests and 72 hours for expedited requests will still result in harmful delays in patient care. **As such, LUGPA *strongly endorses* CMS' alternate proposal for a shorter timeframe that requires prior authorization decisions of 5 days for standard requests and 48 hours for expedited requests.**

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[8] 87 Fed. Reg. 76238, at 76296.
[9] 87 Fed. Reg. 76238, at 76296-97 (noting that CMS does not propose to change the current 15-day standard timeframe, nor the 72-hour timeline for expedited requests, for QHPs on the FFEs).
[10] 87 Fed. Reg. 76238, at 76297.

IV. CMS Should Apply Interoperability, Prior Authorization, and Related Requirements to Medicare Fee-For-Service.

Although the proposals in the Proposed Rule do not directly pertain to Medicare FFS, CMS states it wants to "ensur[e] that all patients with Medicare coverage can benefit from the policies that we are proposing, regardless of [beneficiaries'] coverage or delivery system."[11] As such, CMS is requesting comments on whether the agency should apply the policies outlined in the proposal to Medicare FFS. Specifically, CMS is seeking feedback on recommendations for Medicare FFS to "support improved medical documentation exchange between and among providers, suppliers, and patients," as CMS believes that "it could enable better care for beneficiaries if covered services are not delayed by inefficiencies."[12]

LUGPA appreciates CMS' commitment to ensuring that all patients with Medicare coverage, including FFS, can benefit from the provisions in the Proposed Rule. Furthermore, extending the requirements laid out in the proposed rule will allow for broader uniformity in prior authorization processes amongst coverage types, further decreasing the burden on providers. **As such, LUGPA encourages CMS to apply the interoperability, prior authorization, and related requirements in this Proposed Rule to Medicare FFS.**

V. CMS Should Move Up the Implementation Date for the Policies in the Proposed Rule, Including PARDD API Implementation and Prior Authorization Decision Timeframes.

Throughout the Proposed Rule, CMS affirms the necessity of streamlining processes associated with prior authorization; for example, CMS notes how implementation of the PARDD API will "improve care coordination by enabling enhanced communication about when a prior authorization is required, information that is required to approve a prior authorization, and facilitating electronic prior authorization[,] [which] would add efficiencies for both payors and providers, and could improve patient care by avoiding gaps and delays in care."[13] However, CMS proposes to delay the implementation date for the PARDD API requirement, which includes providing specific information regarding prior authorization denials,[14] and the timeframe for prior authorization request decisions, among others, to January 1, 2026.

LUGPA's mission is to ensure our providers can continue to deliver high-quality, comprehensive patient care, and we appreciate CMS' goals for improving processes for requesting prior authorization, ensuring that patients have timely access to essential care, and reducing administrative burdens on providers; streamlining the prior authorization process will allow providers to focus on patient care. However, the January 1, 2026 implementation date is an unnecessarily long delay, as providers urgently need relief from the burdens associated with current prior authorization processes. **LUGPA therefore respectfully requests that CMS establish an earlier implementation date than January 1, 2026.**

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[11] 87 Fed. Reg. 76238, at 76243.
[12] 87 Fed. Reg. 76238, at 76243.
[13] 87 Fed. Reg. 76238, at 76346.
[14] 87 Fed. Reg. 76238, at 76290, 76292.

VI. CMS Should Not Implement the Proposed 'Electronic Prior Authorization' Measure Under the MIPS Promoting Interoperability Performance Category.

Last, CMS proposes to include a new measure, titled "Electronic Prior Authorization," in the Health Information Exchange (HIE) objective for the Promoting Interoperability performance category under the Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS).[15] This proposal follows a request for comments in the 2020 Proposed Rule, in which CMS sought feedback on mechanisms to incentivize health providers to use electronic prior authorization solutions.[16] Under this new measure, providers participating in MIPS ("eligible clinicians") would report the number of prior authorizations requested electronically from a PARDD API using certified electronic health record technology (CEHRT).[17] Importantly, CMS proposes to require eligible clinicians to report this measure beginning with the calendar year (CY) 2026 performance period. Although CMS states this measure will not yet affect the total score for the MIPS Promoting Interoperability performance category, it also states that it intends to propose a scoring methodology for the measure in future rulemaking.

While LUGPA supports the notion of incentivizing providers as described above, LUGPA opposes this proposal and respectfully requests that CMS not finalize this proposed performance measure and associated reporting requirement. Anticipating a provider obligation to meet a metric for compliance with a requirement where no standards or guidelines of operability or attainability have even begun to be established is premature. Futhermore, LUGPA agrees with CMS' effort to mitigate provider burdens by refining the current prior authorization proces, it is thereby counterproductive to concomitantly create an additional reporting requirement concomitantly. Historical data shows that MIPS compliance is costly and time-consuming;[18] compliance with the new requirements may require the adoption of new technologies and upgrades to existing software. The former may be challenging for practices grappling with the current economic environment and the latter requires vendor-related changes that are out of the provider's control. Consequently, LUGPA also urges CMS to not proceed with rulemaking to score this new performance measure, as MIPS eligible clinicians may be unfavorably evaluated—and potentially subject to a negative payment adjustment—for not having the necessary infrastructure to submit electronic prior authorization requests using a PARDD API with date from CEHRT.

VII. Call to Action

In summary, LUGPA broadly supports CMS' initiative to speeden and streamline the prior authorization process and enhance the use of electronic resources by both payors and providers. LUGPA urges CMS to:

1. Implement the prior authorization API requirements in a manner that is not burdensome to providers;

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[15] 87 Fed. Reg. 76238, at 76312.
[16] 87 Fed. Reg. 76238, at 76311 (citing the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule ("2020 Proposed Rule"), 85 Fed. Reg. 82586, at 82639 (Dec. 18, 2020)).
[17] 87 Fed. Reg. 76238, at 76312.
[18] Khullar D, Bond AM, O'Donnell EM, et. al. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. JAMA Health Forum. 2021;2(5):e210527.

2. Finalize its proposal to shorten timeframes and decisions on standard and expedited prior authorization requests, but decrease the timeframe to require prior authorization decisions of 5 days for standard requests and 48 hours for expedited requests.
3. Apply the interoperability, prior authorization, and related requirements in this Proposed Rule to Medicare FFS.
4. Finalize its proposal to the implement the PARDD API requirement but urges CMS to establish an earlier implementation date than January 1, 2026.
5. Defer implemenatation of its new "Electronic Prior Authorization," in the Health Information Exchange (HIE) objective for the Promoting Interoperability performance category under the Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS) as well as defer rulemaking related to any proposed scoring methodology.

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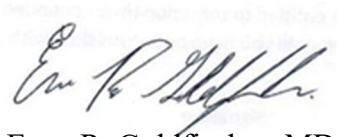
On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Rule. Please feel free to contact Dr. Kapoor at (516)-342-8170 or dkapoor@solarishp.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



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