COLLEGE of AMERICAN PATHOLOGISTS

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 8013, Baltimore, MD 21244-8013

Subject: 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 College of American Pathologists (CAP) appreciates the opportunity to comment on the Proposed Rule CMS-0057-P, which seeks to "improve the electronic exchange of healthcare data and streamline processes related to prior authorization," including within Medicare Advantage (MA). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

As you know, pathologists are physicians whose timely and accurate diagnoses drive care decisions made by patients, primary care physicians, and surgeons. Pathologists are acutely aware that the right test at the right time can make all the difference in a patient's diagnosis, treatment, and outcome. Unfortunately, prior authorization often interferes with a patient's ability to receive timely and appropriate services/care, negatively affecting patients, providers, and the entire health care system. Recent American Medical Association (AMA) survey data show that 93 percent of physicians report care delays or disruptions associated with prior authorization, and as was explained in the HHS Office of Inspector General report that highlighted concerns about prior authorization within MA, inappropriate denials may prevent or delay beneficiaries from receiving medically necessary care and can burden providers. Importantly, to more fully address issues with prior authorization, the proposals here must be implemented together with the reforms in the Proposed Rule for Part C & Part D (CMS–4201–P)[1]. These reforms are needed to improve the coverage criteria used in medical necessity determinations and to ensure a clinically sound foundation for prior authorization programs.

[1] https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2FPA-sign-on-letter-Part-C-and-D-rule.zip%2FPA-sign-on-letter-Part-C-and-D-rule.pdf

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However, in addition, the proposals here include "technical and operational proposals that are intended to improve the prior authorization process." As we have commented before[2], streamlining or automating prior authorization and other utilization management processes is critically important. According to the AMA's prior authorization survey, physicians and their staff spend an average of two business days per week completing the prior authorization workload for a single physician, and 88 percent of physicians describe their prior authorization burden as high or extremely high. And as is explained by the Centers for Medicare & Medicaid Services (CMS) here, "dissimilar payer policies, provider workflow challenges, inconsistent use of electronic standards, and other technical barriers" associated with prior authorization are "major source of burnout for providers."

Thus, while prior authorization processes may help payers to control costs and ensure payment accuracy, the resulting barriers can more often do more harm than good. The CAP is committed to improving patient care and addressing escalating health care costs. Yet, it is imperative that cost-control measures balance other considerations and continue to ensure access to timely and appropriate care. **We applaud CMS for its efforts to "alleviate the burdens of these processes" on patients, physicians, and hospitals, and we strongly support the majority of the changes offered in this proposed rule.** Specifically, we urge CMS to finalize, with some strengthening adjustments, the changes proposed for (1) electronic options for prior authorization (2) requirement for payers to provide status of prior authorization requests and reason for denial of authorization, (3) requirements for prior authorization decision timeframes and communications, (4) public reporting of prior authorization metrics, and (5) "gold carding" programs for prior authorization.

1. Electronic Options for Prior Authorization

As is outlined in the proposed rule, burdens associated with prior authorization include difficulty determining payer-specific requirements for items and services that require prior authorization, inefficient use of provider and staff time processing prior authorization requests and information (sending and receiving), and use of proprietary interfaces and web portals through which providers must submit their requests. We agree with CMS that this ad hoc and inconsistent set of processes is "inefficient, burdensome, and create[s] service issues for patients." Therefore, we support the requirement of a single Application Programming Interface (API) to address these issues, and we stress the goals of streamlining and automating a unified electronic prior authorization system, ensuring consistency across payers and widespread adoption of the technology. As is stated in the Consensus Statement on Improving the Prior Authorization Process, "[t]echnology adoption by all involved stakeholders, including health care providers, health plans, and their trading partners/vendors, is key to achieving widespread industry utilization of standard electronic prior authorization processes."[3]

[2] https://documents.cap.org/documents/cap-prior-authorization-comments.pdf
[3] https://edhub.ama-assn.org/data/multimedia/10.1001ama.2018.0080supp1.pdf

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Further, we understand that with the use of the proposed API, CMS contemplates HIPAA-compliant prior authorization transactions, but we would stress that whether it is the PARDD API, the Patient Access API, the Provider Access API, or the Payer-to-Payer API, CMS must also ensure compliance with the Genetic Information Nondiscrimination Act of 2008 and put in place measures to encourage protection and appropriate use of patient data. Discrimination or patient profiling as a result of accessible patient data could restrict coverage and care, rather than contribute to the important goals of care coordination and increased access.

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

CMS notes that better communication – including timely and specific/clear information from payers about the status of prior authorization or the reason(s) for denial – could help mitigate some of the challenges associated with prior authorization. The CAP strongly supports improved communication and increased transparency from payers, especially including consistent use of technology and terminology.

3. Requirements for Prior Authorization Decision Timeframes and Communications

The CAP appreciates CMS listening to concerns about excessive wait times for prior authorization decisions, whether waiting for the initial request, or for the resolution of a request "in process." We agree that timeframes can directly affect patient care "by delaying access to services, including transfers between hospitals and post-acute care facilities, treatment, medication, and supplies." Current timeframe requirements generally include 72 hours for expedited (urgent) prior authorization decisions, and 14 calendar days for "standard" decisions. We appreciate CMS's proposals to shorten the timeframe for standard decisions to 7 calendar days, and we support CMS efforts to align prior authorization decision timeframes across payers. However, we encourage CMS to shorten the expedited timeframe to 24 hours and the standard timeframe to 48 hours across all payers. Delays associated with prior authorization have serious consequences for patients, ranging from negative effects on clinical outcomes to treatment abandonment. With adoption of the proposals outlined above, which are aimed at making the prior authorization process more efficient, these shorter timeframes should not just be possible but required.

We also urge CMS to adopt policies (audits, penalties, etc.) to ensure enforcement of and accountability on these timeframes, rather than simply having the provider contact the payer if they fail to meet the timeline. Leaving the decision on how to "efficiently support provider inquiries on status should responses or timeframes be missed" up to the payers causing the problem is not an adequate solution.

4. Public Reporting of Prior Authorization Metrics

In this proposed rule, CMS is looking to require payers to "publicly report certain aggregated metrics about prior authorization by posting them directly on the payer's website or via a

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publicly accessible hyperlink(s)." The CAP agrees that transparency regarding prior authorization processes is valuable, and we strongly support the public reporting of payers' prior authorization metrics. However, we are less optimistic about those payers voluntarily using the information "to assess their internal performance" and "contribute to improvements in the prior authorization process," and would suggest CMS use this data to instead require improvements beyond the possibility of incorporating these requirements into quality star ratings across certain payer programs, which we would also support.

Further, this kind of information will be helpful for patients, providers, and the public, and thus must be easy to read, access, and understand (consumer-friendly). At this time, CMS does not propose a format for how to present the aggregated data, however in another area of payer public reporting, even experts have had extraordinary difficulty finding and accessing price transparency data as required by the Transparency in Coverage Final Rule (CMS-9915-F).[4] Therefore, we also urge CMS to finalize additional requirements around the format/posting of these reports to ensure they are uniformly accessible and easily readable.

5. "Gold-Carding" Programs for Prior Authorization

In the proposed rule, CMS explains "gold-carding" as a program where "providers are relieved of requirements to submit prior authorization requests based on data indicating their adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria." Further, as CMS notes, many states are already implementing gold-carding programs to address issues with prior authorization. We applaud the CMS decision to encourage payers to adopt gold-carding approaches, which can alleviate provider burden and "allow clinicians to deliver care in a timely and value-based manner." Indeed, gold-carding programs further the CAP's goal of targeting prior authorization only where it is needed most, and easing the burden on health care providers as much as possible. As CMS notes, requiring prior authorization for "certain items and services that are almost always approved" or for providers who have demonstrated a "consistent pattern of compliance" is neither efficient nor cost-effective. Gold-carding helps in addressing these issues.

We also support CMS's suggestion to incorporate gold-carding as a factor in quality star ratings, as well as a requirement in payer's prior authorization policies. However, we strongly urge CMS to incorporate appropriate protections against retrospective plan denials or reductions to reimbursement applicable to health care services subject to a gold-carding waiver. Especially for pathologists and clinical laboratories who often render health care services at the request of an exempt ordering provider, it is critical to ensure plans cannot retroactively deny coverage after provision of services, which would add administrative burdens or payment reductions for physicians, and ultimately harm patient care – contrary to the public policy intent of prior authorization waivers. The CAP has worked with the AMA on this kind of protection, and offers the following sample language:

[4] https://www.npr.org/sections/health-shots/2022/07/27/1113091782/health-insurance-prices-for-care-are-now-out-there-but-finding-them-is-an-ordeal

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i) A utilization review entity shall not deny or reduce payment for a health care service exempted from a prior authorization requirement under this section, including a health care service performed or supervised by another health care provider, when the health care provider who ordered such service received a prior authorization exemption, unless the rendering health care provider: (1) knowingly and materially misrepresented the health care service in request for payment submitted to the utilization review entity with the specific intent to deceive and obtain an unlawful payment from the utilization review entity; or (2) failed to substantially perform the health care service.

Finally, as CMS looks at improving prior authorization requirements, we would also highlight increasing challenges around laboratory benefits management programs (LBMs), which are health insurance payer protocols or programs that are administered by a health insurance payor or another entity under contract with the payer. These programs often dictate or restrict health care provider decision-making relating to the use of clinical laboratory/pathology services, and the CAP believes that regulation of LBMs is fundamentally needed to prevent conflict of interests by entities that administer these programs, and to ensure that these programs do not conflict with, subordinate, or unduly encumber the practice of medicine.

Again, we applaud CMS for the proposals included in this proposed rule and we sincerely appreciate CMS's attention to the issues with prior authorization. We urge CMS to finalize these changes with some strengthening adjustments – especially in protecting patient data, shortening the timeframes, accountability/transparency, and adding protections against retrospective denials. The College of American Pathologists is pleased to have the opportunity to comment this issue and appreciates your consideration of these comments.

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