



March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington DC 20201

RE: 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 (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

Comments submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide comments on CMS 0057-P, Notice of Proposed Rulemaking on advancing interoperability and improving prior authorization processes. AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise.

AMIA commends CMS for taking steps to address the workflow burden of prior authorization and the significant barriers and delays that it imposes on medical practice. Most importantly, prior authorization impedes timely patient access to needed care and in some cases, results in denial of appropriate care altogether. We believe the provisions of this proposed rule are an important step to improve health care delivery for patients and providers alike and offer the following comments for the Agency’s consideration.

Need for Roadmap

This proposed rule outlines significant process changes to make the prior authorization process more efficient for all stakeholders. Given the broad scope of this rule and the numerous administrative, infrastructure and technical changes that will need to be in place for this to work as envisioned, AMIA suggests that CMS provide an implementation timeline with steps that will need to be taken to ensure all parties are ready for implementation in 2026.

Prior Authorization and Unnecessary, Harmful Care Delays

American Medical Association (AMA) survey data ([AMA prior authorization \(PA\) physician survey \(ama-assn.org\)](#)) (accessed February 27, 2023) show that 93 percent of physicians report care delays or disruptions associated with prior authorization. AMA data also show that 34 percent of physicians report that prior authorization has led to a serious adverse event (e.g., hospitalization, permanent impairment, or even death) for a patient in their care and that 91 percent of physicians see prior authorization as having a negative effect on their patients' clinical outcomes.

Further, the Department of Health and Human Services Office of Inspector General (OIG) last year found that 13 percent of prior authorization requests denied by Medicare Advantage (MA) plans met Medicare coverage rules. ([Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care OEI-09-18-00260 04-27-2022 \(hhs.gov\)](#)) (accessed February 27, 2023).

While AMIA appreciates CMS' attempt to improve care delivery by requiring more prompt payer response times to prior authorization requests, AMIA believes the proposed response times for such requests are too long given the potential for severe, negative consequences that can result from unnecessary delays in care delivery. Urgent (expedited) requests require a payer response within 24 hours, not 72 hours. Non-urgent requests require a response within three business days, not seven calendar days as proposed.

AMIA strongly supports CMS' proposal to add information about prior authorization to the categories of data required to be made available to patients through the Patient Access API. Payers should be required to include information about patients' prior authorization decisions to help patients better understand the payer's prior authorization process and its impact on their health. Most importantly, payers must be required to state the complete reason (s) for any denial of a prior authorization request.

Patient Opt In / Opt Out

Under the Provider Access API section of this proposed rulemaking, CMS proposes to require impacted payers to build and maintain a FHIR Provider Access API to share patient data with contracted in-network providers with whom the patient has a treatment relationship. Data would flow from the payer to the provider's EHR or practice management system, which would allow them to incorporate a patient's data into their records.

CMS proposes to require payers to provide a mechanism for patients to opt out of making their data available to their providers through this API. There must also be a path for patients to opt back in. Given that CMS is not setting requirements for this process, leaving flexibility for payers, we believe this could be a challenge for patients to navigate, especially those who may change payers on a more frequent basis. At a minimum, payers should be required to state, in clear and uniform language, the potential consequences of a patient not allowing a payer to share the patient's information with the patient's provider (s) (e.g., the provider (s) may refuse to provide care to the patient).

Under the Payer-to-Payer Data Exchange provisions of this proposed rule, CMS proposes to require that payers (via FHIR API) exchange patient data when a patient changes health plans with the patient's permission. Those data would include claims and encounter data (excluding cost information), data elements identified in the USCDI version 1, and prior authorization requests and decisions. Payers would be required to define a process for enrollees to opt in to the Payer-to-Payer API data exchange and to identify their previous

and/or concurrent payer(s) prior to the start of their coverage. Again, CMS does not propose requirements for these processes!

AMIA is concerned that this Opt In process could prove confusing for patients without clear and uniform directions provided to the patient prior to the start of their coverage. Patients should also be allowed to opt-in after the start of their coverage, with periodic reminders of the opportunity to opt in. The opt in process will already decrease participation (as opposed to opt out) and lack of a defined process and possible inability to participate (opt in) after enrolling could drive low participation rates.

Standards to Support API Implementation and Recommended Implementation Guides

AMIA strongly supports CMS' efforts to require FHIR-based APIs. FHIR is critical to advance automation and reduce burden. AMIA encourages CMS to further review the technical aspects of this proposal in close consultation with the Office of the National Coordinator (ONC) for Health Information Technology. For example, CMS might consider actions needed to remove the requirement for use of the X12 278 version 5010 transaction standard and instead require use of FHIR solutions. AMIA also encourages CMS to work with ONC on a required standard for Implementation Guides.

Accelerating the Adoption of Standards Related to Social Risk Factor Data

AMIA encourages CMS to further engage ONC and its resources to address standards for the collection of SDOH data. USCDI version 2 contains four SDOH data elements (SDOH Assessment, SDOH Problems/Health Concerns, SDOH Goals and SDOH Interventions) added to support the collection of SDOH data across several SDOH domains.

AMIA supports better integration, interoperability, and bi-directional sharing of data, information, and knowledge across care delivery, public health agencies, and community-based organizations. Especially when addressing the collection of SDOH data, patient privacy must remain paramount in all considerations, with examination of data elements to ensure collection does not ultimately harm already vulnerable patients.

Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

In this proposed rule, as in multiple recent rulemakings, CMS seeks comment on how enabling exchange under TEFCA can advance policies in the CMS *Interoperability and Patient Access* final rule. In this proposal, CMS specifically inquires about use of TEFCA in payer exchange. TEFCA remains immature and as such, it may not be feasible for near-term adoption by payers given the 2026 implementation deadline and the extant architectural and economic concerns associated with its adoption.

Burden Reduction

This proposed rule will impact prior authorization processes for various Medicare and Medicaid payers and their participant providers and hospitals as enumerated in the preamble. Prior authorization as practiced by payers providing coverage for non-Medicare/Medicaid patients may, however, remain onerous for those patients and their providers. One imagines that most payers offering both private and Medicare health coverage would find it operationally inefficient to adopt the improvements envisioned here for the one group while maintaining some version of their legacy systems for patients and providers not subject to these rules. Today providers struggle with payer-specific rules and systems and these proposals without more universal adoption may actually increase the complexity associated with prior authorization processes. We urge CMS to work with ONC to leverage whatever policy levers may exist (e.g., TEFCA payer participation) that would encourage payers to extend these improvements to all their coverage options.

Thank you for your consideration of these comments. If you have any questions, please contact Tayler Williams, AMIA Public Policy Manager, at twilliams@amia.org.

Sincerely,

A handwritten signature in blue ink that reads "Gretchen P Jackson". The signature is written in a cursive style with a large initial "G".

Gretchen Purcell Jackson, MD, PhD, FACS, FACMI, FAMIA
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