American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

October 27, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners, the American Hospital Association (AHA) appreciates the reforms included in the Advancing Interoperability and Improving Prior Authorization Processes proposed rule. The AHA strongly believes that these regulatory changes will alleviate provider administrative burden and improve timely access to care for patients. Accordingly, **we urge the Centers for Medicare & Medicaid Services (CMS) to expeditiously finalize this rule.**

The AHA commends CMS for taking action to remove inappropriate barriers to patient care by streamlining the prior authorization processes for impacted health plans and providers. While prior authorization can be a tool to help ensure patients receive coverage for their care, the practice too often is used in a manner that leads to dangerous delays in treatment, clinician burnout and waste in the health care system. As noted in our March 2023 comments, the proposed rule is a welcome step toward helping patients obtain timely access to care and helping clinicians focus their limited time on patient care rather than paperwork. In particular, we strongly support the agency's proposal to create interoperable prior authorization standards to help address the significant burdens that prior authorization creates for patients and providers.

In the following sections, we enumerate the longstanding need for prior authorization reform and highlight our concern about the largest obstacle to the implementing necessary technological solutions: the X12 278 standard. To truly achieve the benefits of the recommended Fast Healthcare Interoperability Resources (FHIR)-based Application Programming Interfaces (APIs), **we urge CMS to revisit the requirement to transfer FHIR payloads into and out of the X12 278 standard.**

NEED FOR PRIOR AUTHORIZATION REFORM

Although initially designed to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, many health plans apply prior authorization requirements in ways that create dangerous delays in care, contribute to clinician burnout and drive-up costs for the health care system. Prior authorization practices continue to inappropriately impose bureaucratic obstacles to providing patients with the care they need, often jeopardizing patient health in the process.

Patient Care Delays

Prior authorization policies have direct negative impacts on patient care. Ninety-four percent of physicians report care delays associated with prior authorization, and, strikingly, 33% report that prior authorization has led to a serious adverse event for a patient in their care such as hospitalization or death.[1] For example, an AHA member hospital reported treating a man with a deadly skin cancer (metastatic melanoma), requesting imaging scans every three months to assess the progress of ongoing therapies. Unfortunately, the patient's health plan required a new prior authorization for each treatment, a process that frequently delayed the patient's care by weeks at a time, interrupting the timely administration of cancer therapies and disrupting the monitoring of disease progression. Patients deserve health coverage that does not interrupt potentially life-saving treatments that are inherently time sensitive, such as cancer treatment regimens. Such negative patient impacts of prior authorization underscore the critical need to reform the prior authorization process to ensure timely access to needed patient care**.**

Provider Burden

As noted, prior authorization policies burden providers and divert valuable resources from patient care. In response to a recent AHA member survey, 95% of hospitals and health systems reported that the amount of staff time spent seeking prior authorization approval from health plans has increased in the last year. And the resource intensive staff time spent managing health policies adds tremendous cost and burden to the health care system. For example, one 20-hospital system spends $17.5 million annually just complying with health plan prior authorization requirements. And a single 355-bed psychiatric facility needs 24 full-time staff to deal with authorizations.[2] These burdens come at a time when the health care system already is struggling with workforce shortages with wide-ranging consequences for access to care.

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[1] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[2] https://www.aha.org/system/files/media/file/2022/10/Survey-Commercial-Health-Insurance-Practices-that-Delay-Care-Increase-Costs.pdf

Lack of Transparency

As a result of the significant variability between health plans' prior authorization service lists and approval criteria, providers often are uncertain as to whether a particular recommended treatment requires prior authorization and, if so, which documents the plan requires for approval. Currently, obtaining this information requires significant provider and staff time and hassle spent combing through a myriad of payer websites and policy manuals. A large, national health system spends $15 million per month in administrative costs associated with managing health plan contracts, including two to three full-time staff members that do nothing but monitor plan bulletins for changes to the rules.[3] This lack of transparency is a frequent reason that prior authorization and claims are delayed or denied. Leaving providers in the dark about what documentation they must provide results in extensive back and forth between providers and plans, which only serves to delay care and unnecessarily burden clinical staff with resource-intensive paperwork. The CMS proposal to create an automated process for determining services requiring prior authorization and the requisite clinical information needed for adjudication has the potential to substantially improve this issue.

Varying and Inefficient Submission Methods

One of the most frustrating aspects of prior authorization for providers is the variation in submission processes. Plans vary widely on how to format and submit prior authorization requests and supporting documentation. While some plans accept electronic means, the most common method remains using fax machines and contacting call centers, with regular hold times of 20 to 30 minutes. In addition, plans offering electronic methods of submission most commonly use proprietary plan portals, which require a significant amount of time spent logging into a system, extracting data from the provider's clinical system and completing idiosyncratic plan requirements, thereby reducing the administrative efficiencies of the process. For each plan, providers and their staff must ensure they are following the correct rules and processes, which may change from one request to the next. The creation of a standard method for the submission and processing of prior authorizations will not only alleviate provider burden but also ensure that patients have timely access to care.

In light of these burdensome realities, the AHA strongly supports prior authorization reform, including adoption of electronic prior authorization processes that have the ability to streamline the arduous process to improve patient care and reduce provider burnout. We applaud CMS for taking these important steps to require plans to implement these critical prior authorization and electronic data exchange reforms.

[3] Example provided by an AHA member hospital.

FHIR AND THE X12 278 STANDARD

In our March 2023 comment letter, the AHA enumerated various ways to improve upon the proposed rule, including ensuring that the recommended Da Vinci implementation guides have been thoroughly tested and have reached sufficient maturity for widespread adoption. In follow up to these comments, **we are writing to expressly reiterate our strong and continued concern that maintaining the HIPAA X12 278 standard for prior authorizations is a substantial and wholly unnecessary roadblock inhibiting the transformation of prior authorization processes.**

Providers and payers are most likely to succeed in working together to automate prior authorization processes if they are empowered to fully leverage the capabilities of modern API technologies. As part of the Prior Authorization Requirements, Documentation and Decision (PARDD) API, CMS recommends that plans implement the FHIR-based Prior Authorization Support (PAS) IG that gives providers the capability to send prior authorization requests and receive responses electronically within their existing workflow. We strongly support the use of EHR technology for the submission and processing of prior authorizations, as it empowers providers to utilize this information during treatment planning and creates the potential for meaningful, real-time access to this data. However, as noted in both the AHA's comments on the 2020 Reducing Provider and Patient Burden by Improving Prior Authorization NPRM and the 2022 ONC RFI on Electronic Prior Authorization Standards, we harbor concerns regarding the requirement to use the X12 278 in conjunction with FHIR API technology, as the X12 278 transaction does not serve a meaningful purpose and is seemingly included solely to maintain HIPAA compliance.

The current X12 278 standard has proven insufficient in promoting increased administrative efficiencies. While much of the limited implementation of the X12 278 can be attributed to the lack of an attachment standard for submitting supporting clinical documentation, continued required use of the standard stymies the benefits and flexibilities that may be realized through FHIR. Furthermore, the requirement to utilize the X12 278 transaction has hindered the design and development of FHIR-based standards by industry stakeholders. CMS' current proposal to maintain the X12 278 standard would perpetuate this challenge. **Translating FHIR payloads to the X12 278 transaction increases burden, limits FHIR enhancements unsupported by the X12 278 standard, and inhibits the ability to leverage capabilities of FHIR APIs that could advance the automation of prior authorization processes**.

Moreover, the needless translation into and out of the X12 278 transaction will require an intermediary between the provider's and the payer's FHIR-based systems. This will add extra steps and costs to the process and make the transaction more vulnerable to errors. Taken together, we believe these obstacles run contrary to HIPAA's administrative simplification goals as CMS' proposed policy merely serves to increase the burden, cost and technical complexities of prior authorization.

Perhaps the most critical hindrance to reforming prior authorization processes is that the mapping between FHIR and the X12 278 is problematic and incomplete. There is no comprehensive and operational mapping between FHIR and the X12 278, and the unfinished mapping available at present has not been properly vetted or tested, thereby compounding the technical hurdles presented by the need to translate into and out of the X12 278.

As illustrated by the Da Vinci HIPAA Exception approved by CMS through July 14, 2024, the PAS IG enables a FHIR-to-FHIR transaction without unnecessary X12 278 translation. Accordingly, **we strongly urge CMS, under the secretary's authority, to leverage its HIPAA standard setting authority to permit the use of FHIR-based APIs for prior authorization transactions without the requirement to translate between FHIR and the X12 278 standard.** That will enable industry stakeholders to decouple the design of FHIR-based implementation guides for prior authorization from the X12 278 transaction standard and provide greater flexibility to create innovative and automated API-based prior authorization workflows. Once the industry coalesces around mature FHIR-based implementation guides for prior authorization, CMS could require adoption of that standard to minimize fragmentation in the industry and ultimately improve patient access and care.

CONCLUSION

Thank you for your attention to the comments we have raised. We particularly appreciate CMS' thoughtful proposals to alleviate provider burden and improve patient care and access. **We urge CMS to expeditiously finalize the Advancing Interoperability and Improving Prior Authorization Processes proposed rule.** The AHA is pleased to be a resource on these issues and welcomes any opportunity to provide any additional insight that would be helpful to the agency as you plan for future rulemaking. Please contact me if you have any questions, or feel free to have a member of your team contact Andrea Preisler, AHA's senior associate director for administrative simplification policy, at apreisler@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President

Cc: Stella Mandl, Acting Deputy Director, CMS Office of Burden Reduction & Health Informatics