American Hospital Association™

Advancing Health in America

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March 18, 2022

The Honorable Micky Tripathi
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology (ONC)
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Re: Office of the National Coordinator for Health IT Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria

Dear Dr. Tripathi:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, the American Hospital Association (AHA) appreciates the opportunity to comment on the Office of the National Coordinator for Health Information Technology request for information related to electronic standards for prior authorization. We commend you for taking action to remove inappropriate barriers to patient care by streamlining prior authorization processes.

While prior authorization can be a helpful tool for ensuring patients receive appropriate care, the process is too often used in a manner that leads to dangerous delays in treatment, clinician burnout and waste in the health care system. The request for information is a welcome step toward helping providers focus their limited time on patient care rather than paperwork. **The AHA strongly supports the creation of a useable, scalable and efficient solution to help reduce prior authorization impacts on patients and providers. However, we urge ONC — in collaboration with the Centers for Medicare & Medicaid Services (CMS) — to pilot the technologies and workflows described in the rule prior to taking any regulatory steps, including certification or codification of standards to minimize unintended negative consequences, such as an inadvertent increase in costs or burden in the health care system.**

Background

According to America's Health Insurance Plans, prior authorization is implemented by health plans "to help ensure patients receive optimal care based on well-established evidence of efficacy and safety, while providing benefit to the individual patient."[1] Philosophically, we agree with these laudable goals, and, indeed, some health plans use prior authorization in ways that accomplish them. However, 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.

Inefficient prior authorization can negatively impact the quality of care. According to a 2021 American Medical Association survey of more than 1,000 physicians, 91% of respondents indicated that prior authorization "had a significant or somewhat negative clinical impact, with 34% reporting that prior authorization had led to a serious adverse event such as a death, hospitalization, disability or permanent bodily damage, or other life-threatening event for a patient in their care."[2] The federal government also has acknowledged the risk of delays in care caused by prior authorization requirements, which is why it urged health plans to ease such requirements during the COVID-19 public health emergency, stating "New guidance for individual and small group health plans encourages issuers to utilize flexibilities related to utilization management processes, as permitted by state law, to ensure that staff at hospitals, clinics, and pharmacies can focus on care delivery and ensure that patients do not experience care delays."[3]

Prior authorization puts a heavy burden on clinicians and contributes to workforce burnout. According to the National Academies of Medicine, "Among clinicians, burnout is associated with job demands related to workload, time pressure, and work inefficiencies, such as burdensome administrative processes which divert clinicians' attention away from patients and detract from patient care."[4]

The use of standardized electronic prior authorization transactions have the potential to save patients, providers, and utilization review entities significant time and resources and can speed up the care delivery process. **In order to effectively update and create standard transactions without unduly burdening health care payment processes, regulators should approach potential changes judiciously. Any**

[1] America's Health Insurance Plans, "Prior Authorization Frequently Asked Questions." Accessed at: https://www.ahip.org/wp-content/uploads/Prior-Authorization-FAQs.pdf
[2] American Medical Association, "2021 AMA Prior Authorization (PA) Physician Survey." Accessed at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[3] Centers for Medicare & Medicaid Services, "CMS News Alert." Accessed at: https://www.cms.gov/newsroom/press-releases/cms-news-alert-april-23-2020
[4] National Academy of Medicine, "Taking Action Against Clinician Burnout: A Systems Approach to Professional Well-Being." Accessed at: https://nam.edu/wp-content/uploads/2019/10/CR-report-highlights-brief-final.pdfhttps://nam.edu/wp-content/uploads/2019/10/CR-report-highlights-brief-final.pdf

substantial change in the technology and/or standards used in health care information exchange should be sufficiently tested to ensure functionality, analyzed to establish projected return on investment, and incorporated according to an appropriate glide path to minimize systematic disruption.

Certified Health IT Functionality

One of the most frustrating issues with prior authorization for providers and patients is the variation in plan submission processes. Plans vary widely on accepted methods of prior authorization requests and supporting documentation submission. 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, inserting information into the payer's portal, and adhering to idiosyncratic plan requirements, thereby reducing the administrative efficiencies of the process. Additionally, this process of transposing electronic health record (EHR) information into payer portals often leads to entry errors, resulting in denials for medically appropriate procedures that must be reprocessed or appealed and can delay patient access to care. **Therefore, we strongly support an end-to-end automated prior authorization process that integrates with clinicians' EHR workflow. The use of EHR technology for the submission and processing of prior authorizations empowers clinicians to utilize this information during treatment planning and creates the potential for meaningful, real-time access to this data.**

Congress recognized the importance of standardizing the prior authorization workflow when it included the transaction in its administrative simplification provisions under the Health Insurance Portability and Accountability Act (HIPAA). Unfortunately, adoption of the HIPAA standard transaction for processing prior authorizations (X12 278 Healthcare Service Review and Response) has been extremely poor, due in part to the failure to establish an attachment standard for submitting supporting clinical documentation. As such, we have concerns with the reference in the Request for Information to the continued use of the 278 transaction in tandem with the Da Vinci Prior Authorization Support (PAS) application programming interface (API).

In order to be compliant with the HIPAA regulations, the PAS Implementation Guide (IG) requires the FHIR-API prior authorization information to be translated into the 278 transaction for transmission to the health plan, at which point it would be translated back to FHIR. The translation of FHIR information into and out of the 278 transaction would likely require providers to procure additional clearinghouse services in order to successfully complete the transaction, which runs contrary to HIPAA's administrative simplification goals and undermines the provider and industry savings achieved in the process. Absent additional benefits or efficiencies created through the FHIR-to-X12

translation process, a standard process should not require translation from FHIR, and we recommend the continued granting of HIPAA exceptions to pilot direct FHIR-to-FHIR exchange for Da Vinci IGs. This will allow the industry to test this new technology and inform any future decisions regarding prior authorization electronic standards under HIPAA.

Implementation Specifications for Prior Authorization

The AHA fully supports ONC's interest in streamlining prior authorization by utilizing new technology to increase consistency and timeliness in these processes. However, we caution against premature implementation of a solution that has yet to be completed and tested to ensure functionality in a real-world environment.

The proposed IGs are at the standard for trial use (STU) ballot level and are not yet normative (i.e. finalized). According to HL7, an STU ballot classification "is used to vet content that is deemed 'ready to implement' by a sponsoring work group, but where there has not yet been significant implementation experience."[5] In fact, the recommended IGs are currently out for ballots, after which they will inevitably undergo revision. **As a process that impacts not only provider resources but also patient access to care, the AHA recommends that any prior authorization solution be fully developed and tested prior to wide scale industry rollout.** This process should include careful consideration as to the transactions scalability, privacy and necessity of access to the transmitted health information and ability to complete administrative tasks in a real-world setting, rather than a controlled environment such as an HL7 Connectathon.

Additionally, real-world analysis needs to be conducted to ensure consistency across API usage. Variance in API usage and how the FHIR transaction is implemented could require significant added vendor services to navigate, which will increase provider costs, thus undermining savings and process simplification. Streamlining API usage would allow for providers and patients to access and share data in simpler and more efficient ways to reduce burden and enhance patient care. Consistent use across providers and payers allows for the industry to fully leverage API tools to transform the patient and provider experiences. Moreover, we encourage such API solutions to incorporate the ability to ensure that providers who are not subject to prior authorization (e.g. due to cost-sharing arrangements, "gold card" processes, etc.) are alerted of this in real-time and do not need to navigate any of the processes.

Robust pilot testing would not only ensure that the transaction is truly ready for real-world usage, but also provide important data on the beneficial improvements achieved through usage of the transaction (e.g. reduced delays, elimination of administrative

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[5] Health Level Seven, "HL7 Balloting." Accessed at: https://confluence.hl7.org/display/HL7/HL7+Balloting

burden). Proof of adequate return on investment will inevitably be critical to convincing providers and plans to undertake the significant technology investments and workflow adjustments needed to utilize the IGs.

Request for Comments: Healthcare Attachment Standards

The need for a standard method of attaching clinical data to claims has been recognized repeatedly since Congress enacted the HIPAA administrative simplification provisions, which called for the creation of a claims attachment standard to facilitate the exchange of such information. Despite legislative requirements (HIPAA and the Patient Protection and Affordable Care Act), significant industry recommendations seeking action (including numerous National Committee on Vital and Health Statistics (NCVHS) letters recommending adoption), and the creation of transactions to meet the industry need, the attachments transaction has yet to be standardized via regulation. This vacancy has significantly hindered automation and administrative simplification when transactions require supporting clinical data, as evidenced by the low adoption of the 278 transaction mentioned above. As a result, the AHA is supportive of the adoption of an attachment standard.

While recognizing the necessity of an attachment standard, the AHA does not have a specific recommendation regarding the format. We urge ONC to evaluate the usefulness of each format both today and moving forward, particularly in light of the status of the prior authorization solution discussed above. For example, since the prior authorization IGs do not utilize the attachment transaction, the usefulness of the attachment for this purpose depends on the potential timeframe of any FHIR-based solution. If regulators launch a substantial testing period to ensure the viability and efficiency of the solution, as we have recommended, an attachment standard utilizing the widely available C-CDA format may be most appropriate for the industry, which could utilize this format paired with the 278 transaction to accomplish prior authorizations in the nearer future. Alternatively, if the industry shifts utilization of API format sooner rather than later, it may not make sense to utilize an alternate clinical format for prior authorizations versus general clinical attachments. Ultimately, while the certification of a national attachment standard would represent a significant advancement, we urge regulators to be prudent in requiring massive technological changes to ensure that providers have the resources necessary to implement the standard.

Impact on Patients

Inappropriate use of prior authorization can negatively impact patient care. A survey of more than 1,000 physicians found that more than 93% of respondents said prior authorization results in delayed patient access to necessary care. Prior authorization approvals can take anywhere from a few hours to a few weeks and, as a result, can get in the way of delivering quality care. Treatment delays can then lead to treatment

abandonment, worsening of conditions, and serious adverse events including hospitalization, disability, or even death. Therefore, we applaud ONC for taking this important step to seek stakeholder input on how best to accelerate and streamline the adoption of electronic prior authorization standards.

As discussed above, we believe the standardization of prior authorization has the potential to meaningfully improve patient health care experiences. The IGs significantly increase transparency of services subject to prior authorization and promote a substantial reduction in the time it takes to complete and successfully transmit prior authorization requests. This increased efficiency should enable health plans to issue determinations in a more rapid timeframe, as they should no longer have to account for slow submissions from providers. This reduction in delays and improvement in processing could allow patients to receive medically necessary care as scheduled without the obstacles that current prior authorization processes often present.

In order to ensure that procedural improvements realized from a successfully piloted and proven solution are passed onto patients, we recommend that any regulation standardizing prior authorization feature requirements that health plans issue prior authorization determinations in a timelier manner. In order to prevent the detrimental impacts on patient care, the AHA recommends that prior authorizations determinations be issued within 72 hours for standard requests, and 24 hours for urgent matters.

Additionally, although standardization of the process represents a significant opportunity to improve patient outcomes, it should not be viewed as a cure-all for provider prior authorization. In addition to automating the current burdensome processes, patients deserve additional reform, including:

- Increased oversight to ensure that health plans are not denying medically appropriate care;
- Controls over the application of prior authorizations to ensure that it is only applied to services with high costs or a history of overutilization; and
- Requirements that plans process prior authorizations at all times, rather than only during standard business hours.

Impact on Providers

Prior authorization policies burden providers and divert valuable resources from patient care. For example, one 17-hospital system spends $11 million annually just complying with health plan prior authorization requirements, and a single 355 bed psychiatric facility needs 24 full-time staff members to deal with prior authorizations. Additionally, a large, national 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.[6] Physicians report that they and their staff spend about two days per week completing prior authorizations, and 88% of physicians describe the burden associated with prior authorization as high or extremely high.[7] **Therefore, the AHA strongly supports prior authorization reform, including adoption of electronic prior authorization processes that have the capacity to streamline the arduous process to improve patient care and reduce provider burnout.**

The AHA is supportive of technological advancements that have been shown to improve safety, quality and efficiency of care for patients. The Da Vinci IGs discussed in this RFI have a real chance of achieving such goals. However, the incorporation of new technology can be an extremely resource-intensive process for hospitals and other providers, requiring systematic updates, testing, personnel education and training, workflow adjustments and potential policy changes all while performing their standard revenue cycle functions. As discussed above, we believe substantially more testing and piloting of these solutions is necessary not only to ensure the applicability of the guides, but also to create the data needed to show providers that the investments and workflow changes needed to implement this solution are worthwhile. Particularly amidst the extreme financial strain that the ongoing pandemic has placed on many hospitals, the investment of such resources may be limited only where there are recognizable, tangible and substantial benefits. Ensuring sufficient provider participation in testing the standards will be crucial in evaluating their viability and readiness for more widespread implementation across payers and providers.

Thank you for the opportunity to comment on this important topic and for your attention to the concerns we have raised. Please contact me if you have any questions or feel free to have a member of your staff contact Terrence Cunningham, director of policy, at tcunningham@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President

Cc: The Honorable Chiquita Brooks-LaSure
        Mary G. Greene, M.D.

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[6] American Hospital Association, "Addressing Commercial Health Plan Abuses to Ensure Fair Coverage for Patients and Providers." Dec. 2020. Accessed at: https://www.aha.org/system/files/media/file/2020/12/addressing-commercial-health-plan-abuses-ensure-fair-coverage-patients-providers.pdf
[7] American Medical Association, "2021 AMA Prior Authorization (PA) Physician Survey." Accessed at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf