March 25, 2022

The Honorable Micky Tripathi
National Coordinator for Health IT
Department of Health and Human Services
Mary E. Switzer Building
Mail Stop: 7033A
330 C Street SW
Washington, DC 20201

Re: RIN 0955-AA04, Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria,

Comments submitted electronically via www.regulations.gov

Dear National Coordinator Tripathi:

The American Medical Informatics Association (AMIA) appreciates the opportunity to respond to the RFI on electronic prior authorization standards, implementation specifications, and certification criteria that could be adopted within the ONC Health IT Certification Program.

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. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.
Seven AMIA member experts formed a work group to prepare this response to the RFI, and its content was reviewed by the AMIA President and Board Chair. AMIA commends ONC for this solicitation of feedback and its stated recognition of the multiple stakeholder constituencies implicated in this area of evolving regulatory framework.

Consistent with our comments to the Centers for Medicare and Medicaid Services (CMS) last year, we support efforts to address prior authorization workflow through application program interface (API) standards. We support CMS's intent to provide more specific guidance to implementers and agree that more consistent exchanges between payers and providers could reduce current burdens if implemented thoughtfully. While the goals are laudable, proposals must also address the underlying causes of prior authorization burden. New EHR certification criteria are needed and we have previously recommended that CMS establish industry adoption timelines for health IT.

The goal of streamlining the prior authorization process through FHIR-enabled APIs will only ultimately be successful if these requirements are built into certification. We have urged CMS to determine such adoption requirements.

We provide the following comments for feedback to ONC's request for information.

1) Functional capabilities for electronic prior authorization in certified health IT

Development of consistent standards for data and/or supporting documentation required from providers should be mandatory for payors to participate in future automated Health IT systems for prior authorization. While some variation is necessary for certain specialties and unique clinical scenarios, more consistency in the data required could allow for more automation and decrease the administrative burden on providers and administrative staff. Consider incentivizing payors to participate in future standardization and automation solutions.

2) Additional approaches to support electronic prior authorization: healthcare attachments

ONC notes there are existing capabilities and standards currently supported by certified health IT products that may facilitate certain elements of prior authorization workflows. This includes supporting clinical documents for a broad range of use cases, including for attachments within prior authorization and other administrative workflows.

ONC should provide guidelines and test examples to verify the integrity of healthcare attachment implementation and demonstrate the effectiveness of the implementation per vendor. The timeline for implementation should have a two-track goal: soft implementation of the exchange, with a hard implementation deadline to follow. There is a need to promulgate timelines which responsibly address the need to mitigate prior

authorization burdens on the patient and provider communities, while giving adequate time for compliance by public and private payers.

The FHIR Documents would facilitate better exchange. Given the support around FHIR implementation in other Health IT sectors, it would also provide support for other applications built on the FHIR protocol. While having both approaches of Clinical Document Architecture (CDA) Attachments and FHIR Documents could benefit implementation of prior authorization reforms, it would inevitably lead toward confusion and potential issues of interoperability. Therefore, the most appropriate protocol to adopt would be FHIR Documents.

3) Impact on providers

Prior authorization leads to disruptions in clinical practice and workflow management. In an environment where clinicians are asked to manage an increasing number of patients with complex and co-morbid conditions, achieving uniform electronic prior authorization processes will ease clinician burden.

- Integrated electronic prior authorization could reduce fragmentation between payer and prior authorization systems by making sure payer information is up-to-date, or by reducing the number of misfirings or misclassifications of medications that may not currently require prior authorization, thereby decreasing cognitive load and burden for providers.
- Computerizations of prior authorization will not alone be the answer to better efficiency or higher adherence to treatment plans. A problematic situation would arise if not all payers participate in the use of an integrated system or network, requiring providers to track the payers that participate and those that do not. Lack of participation creates further gaps in information processing and generalizability of workflow between those who are connected and those who are not.
- Providers are burdened by two care delivery systems. One that supports only traditional prior authorization systems that include phone, fax, etc., and another which uses electronic prior authorization. An estimated 75% of providers who use electronic prior authorization also use other prior authorization methods.[1] These two different delivery systems require different workflows and when used concurrently create additional time constraints and inefficiencies in patient management.

Creating a system that aligns with the most efficient and safe workflows to support providers and patients is the most important goal. These systems must each be evaluated on their own merit. For example, electronic prior authorization may create some efficiencies in workflow, but if the efficiencies in workflow begin to create time

constraints, such as requiring the provider to address many in-basket messages about denials and approvals, the efficiency may be lost and patient care could suffer. Therefore, research using user centered design approaches to evaluate the impact of different systems of prior authorization and their workflows on providers and patients is critically needed during each step of the systems life cycle.

- There are a multitude of problems with prior authorization that good human centered design principles and standardization could address (e.g., electronic portals do not always provide correct forms. Providers must interface with multiple pharmacy benefits managers (PBMs), each with unique formulary, PA forms and formats).[2]

4) Impact on patients

AMIA is concerned about the barriers to patient care that result from prior authorization processes. Access to essential care is often delayed due to burdensome prior authorization requirements.

- Electronic prior authorization could enhance capabilities to suggest medication alternatives rather than outright rejecting medications. This could help patients understand what alternative medications are available as they make their healthcare decisions.
- The impact of out-of-pocket costs to patients for development and implementation of different types of prior authorization systems must be understood. This is critical especially if increased costs do not lead to more efficient and enhanced care delivery. Electronic prior authorization systems may not alleviate the differences across insurance plan formularies which can create fragmentation and make communication difficult. As we invest in these technologies, we need to ensure that underlying differences are addressed. Further, there could be a lack of transparency for patients with electronic delivery for the reasoning behind payer choices in offering treatments. This could reduce trust in the care provided and potentially increase health care disparities.
- The 2022 Medication Access Report found that 21% of patients experienced a delay in receiving medication over the last 12 months due to prior authorization.[3]

AMIA believes that including prior authorization information as part of a Patient Access API is ultimately essential. However, we note that considerable development by information technology providers would be required. Until patient-facing third-party apps are better able to consume data from prior authorization APIs, we believe that the gain will ultimately be minimal. Solving this problem will require patient-facing app developers, payers, and providers to coordinate.

5) Payer implementation

There is a need for payers to partner and collaborate with the informatics communities to best configure processes, innovation, and resources to improve and streamline prior authorization practices, with a goal of minimizing inefficiencies for patients and providers. AMIA would be pleased to serve as a resource to the payer community as the regulatory framework takes shape.

Thank you for your consideration of these comments. Should you have any questions or require additional information, please contact Tanya Tolpegin, AMIA Chief Executive Officer, at ttolpegin@amia.org.

Sincerely,

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2. Bhattacharjee S, Murcko AC, Fair MK, Warholak TL. (2019). Medication prior authorization from the providers perspective: A prospective observational study. Research in Social and Administrative Pharmacy. 15(9):1138-1144. doi: 10.1016/j.sapharm.2018.09.019. Epub 2018 Sep 26. PMID: 30279130.
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