March 22, 2022

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Micky Tripathi, PhD, MPP  
National Coordinator for Health Information Technology  
Office of the National Coordinator for Health Information Technology  
330 C St SW  
Washington, DC 20201

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

Dear Secretary Becerra and Dr. Tripathi:

On behalf of the American Academy of Family Physicians (AAFP), which represents 127,600 family physicians and medical students across the country, I write in response to the request for information, *Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria* as requested by the January 24, 2022 Federal Register.

Prior authorization continues to be a leading cause of physician burden and therefore the AAFP is strongly supportive of efforts to reform and streamline the prior authorization process. To deliver clinically appropriate care to their patients, family physicians must navigate prior authorization requirements that can add significant cost and time burdens on their practices. In the most recent American Medical Association (AMA) survey of physicians, 88 percent of respondents reported that prior authorization generates high or extremely high administrative burden for their practices. Practices complete an average of 41 prior authorizations per physician per week, spend an average of almost two business days a week completing prior authorizations, and 40 percent of respondents reported that they have secured additional staff to work exclusively on prior authorization, including keeping up with varied requirements across payers.

Prior authorization requirements have grown over the years and throughout the COVID-19 pandemic, exacerbating barriers to care during this challenging time. A recent poll of medical groups found 81 percent of respondents felt prior authorization requirements increased since 2020, indicating no flexibility or changes from health plans during this time where access to care has been strained. What’s more, the burden from increased requirements is compounded by the labor shortage coinciding with the pandemic, which has affected practices’ ability to recruit and retain practice staff and appropriately complete prior authorization requests.
Not only do these requirements negatively impact practice workflows and physician wellbeing, but evidence also shows prior authorization can harm patients by delaying care, confusing patients, and resulting in reduced adherence to treatment or even discontinuation of treatment, all resulting in increased morbidity and mortality. In the same AMA survey, 34 percent of physicians reported that prior authorization has led to a serious adverse event for a patient in their care and additional outcomes such as patient hospitalization, secondary intervention to prevent permanent damage, and permanent bodily damage or death have been reported as associated with prior authorization. Overall, 91 percent of physicians report prior authorization has a negative impact on patient clinical outcomes.

Even when physicians complete prior authorization requirements, payers often do not sufficiently respond to prior authorization requests in a timely manner. California-based L.A. Care failed to address a backlog of more than 9,000 prior authorization requests and more than 67,000 complaints or appeals. These unresolved requests led to negative impacts on patients, including delays in needed care, increased emergency department visits, and even death.

Evidence indicates that prior authorization requirements may be discriminatory and worsen health disparities, as documented in a study examining access to treatment for HIV pre-exposure prophylaxis and a white paper which examined the disproportionate impact of prior authorization requirements on cardiovascular care for Black and other patients of color. We are concerned that prior authorization requirements can worsen health disparities and create barriers to care for medically underserved patients, patients of color, LGBTQ+ patients, patients in rural areas, and those at risk for poor health outcomes. Federal oversight and action is needed to address the negative impacts prior authorizations are having on patients and physicians.

AAFP applauds ONC for working to automate prior authorizations to lessen the burden on physicians. However, this burden and the resulting care delays cannot be eliminated, or even meaningfully reduced, by automating the existing workflows and volumes of prior authorizations. Electronic prior authorization is just one step in addressing the flaws of utilization management practices and comprehensive reform is needed to reduce the volume of prior authorizations and ensure patients' timely access to care. We urge you to collaborate with CMS and other relevant agencies to review prior authorization from all angles and work to reduce unnecessary complexity where warranted. The AAFP looks forward to working with HHS to increase oversight of prior authorization, reduce the volume of prior authorizations, increase transparency of prior authorization requirements, and streamline prior authorization processes.

Certified Health IT Functionality

Do the functional capabilities described include all necessary functionality for certified Health IT Modules to successfully facilitate electronic prior authorization processes? Are there additional capabilities that should be included in certified Health IT Modules to address these needs? Should any of these functional capabilities not be included in Certified Health IT Modules or should ONC focus on a more limited set of functional capabilities for certified Health IT Modules than those described?

We appreciate the functional capabilities included in the RFI and recommend including all of them in certified health IT to successfully facilitate electronic prior authorization. Overall, ONC should ensure that standards make up-to-date prior authorization requirements for all health plans readily available.
to the physician, while minimizing the need to navigate between different screens. Specifically, identifying when prior authorization is applicable using clinical decision support, receiving notification of any changes in applicability, identifying specific rules and documentation requirements, collecting clinical and administrative documentation needed to complete prior authorization documentation, and receiving a response from a payer on approval, denial, or need for additional information are all elements to create a solid foundation for prior authorization processes. These capabilities are also consistent with the joint Prior Authorization and Utilization Management Reform Principles, which the AAFP supports.

The principles state prior authorization and other utilization management review processes should be clinically valid, fair and transparent, and efficient. Utilization management should be based on accurate and up-to-date clinical criteria, and electronic prior authorization functionalities should make this information readily available to the ordering physician, as well as to patients if a patient access application program interface (API) is widely adopted or required by CMS. The standards should also clearly indicate the expected timeline for a response, ensure physicians are able to easily access payers’ rationale for denying a request, and outline the process and documentation needed to appeal a decision.

**Implementation Specifications for Prior Authorization**

*What is the current readiness of the three FHIR-based Da Vinci IGs for adoption as part of certification criteria for health IT?*

We recommend ONC continue to drive the adoption of standards and implementation guides (IGs) that have been proven in the real-world. Standards and IGs are important for facilitating the availability and adoption of electronic prior authorization processes. However, implementing standards before they have been fully vetted and tested can worsen physician burden and care delays. **Only standards and IGs that have been proven effective and adoptable in real world testing should be candidates for mandatory certification and utilization**, including the Da Vinci standards.

ONC seeks comment on whether the capabilities and processes listed in the RFI are sufficient to successfully facilitate electronic prior authorization. We believe real world testing is the best way to understand whether current standards truly automate prior authorization from end to end in a way that reduces administrative burden. Robust real-world testing can also mitigate the issues we have seen with the implementation of other health IT standards, such as (1) repeated delays in regulatory mandates due to industry readiness or adoptability issues, (2) the availability of only partial solutions (i.e., the mandated standards are insufficient to get the intended market change), (3) and the introduction of physician burden and other unintended consequences.

**Impact on Patients**

*How could potential changes reduce the time for patients to receive needed healthcare services, reduce patient non-adherence, and/or lower out-of-pocket costs?*

Adopting electronic prior authorization standards may help improve patients’ timely access to care. Existing survey data indicates that prior authorizations cause care delays, abandonment of needed care, and even adverse events. Implementing prior authorization standards could shorten the wait
time between when a prior authorization request is made by a physician and when it is ultimately approved by the payer. This could reduce costs if a patient can receive treatment on the same day as their original appointment instead of having to return and pay an additional copay.

However, electronic prior authorization alone will not eliminate the care delays or other negative health impacts of prior authorization. In many cases, patients will still have to wait to get the treatment or service they need. Further, its likely payers will continue to deny prior authorization requests for evidence-based services and require physicians to do a peer-to-peer review or otherwise appeal the decision, which is a time intensive process that continues to delay care.

Patients also will continue to experience delays if standards are adopted and required before they are fully functional and effective in the real world. More comprehensive reform is needed to mitigate the negative impacts of prior authorization on patients.

**Impact on Physicians**

*To what degree is availability of electronic prior authorization capabilities within certified health IT likely to reduce burden for healthcare providers who currently engage in prior authorization activities?*

Once standards are fully implemented and functional, automating prior authorization will help streamline the process so long as EHR vendors and payers have fully adopted the standards and made them readily available to physician practices. For example, electronic prior authorization will minimize the need to navigate across different screens and websites to determine whether a prior authorization is required and what documentation is needed. That said, electronic prior authorization alone will not substantially reduce burden for physicians and other health care clinicians who engage in prior authorization activities. Physicians will still need to fill out prior authorization forms to justify the need for too many treatments and services, as well as answer questions payers may have in response to the request, and complete peer-to-peers or other appeals processes.

While we are supportive of advancing electronic prior authorization standards, we recommend ONC increase its focus on developing and driving the adoption of standards that would support physicians and their teams in providing high-quality, evidence-based care. Additional efforts are needed to efficiently bring needed clinical and financial knowledge to the point of care within the workflow of ordering and decision making in real-time. This would support the physician at the time of order creation instead of determining if a service the physician has already recommended warrants coverage and payment, which delays patient care and interferes in the patient-physician relationship. Clinical decision support may help alleviate some burdens from prior authorization by facilitating care decisions based on available evidence, recommendations, and guidelines. However, clinical decision support alone is not likely to substantially reduce burden and should not be considered a solution or alternative to prior authorization.

Relatedly, we urge ONC to work with CMS to establish guardrails for payers’ ability to access EHR data and influence medical decision making. By allowing payers to automate query into CEHRT or to insert information at the point of care (e.g., CDSHooks card), they are able to influence physicians’ medical decision-making process. The proliferation of arbitrary prior authorization requirements imposed by payers illustrates the need for a framework that governs how automated queries can be used by payers, as well as additional measures to require transparency. Because inserting
information at the point of care can impact clinical decision making, guardrails are needed along with the ability to study and audit the use of these functions. ONC should also consider a similar framework, as well as data segmentation, for how payers can ultimately use data pulled for prior authorizations. For example, this data should never be used when renewing a contract with a physician practice.

To what degree are healthcare providers likely to use these new capabilities across their patient panels? Will additional incentives or requirements be needed to ensure healthcare providers efficiently use these capabilities? What accompanying documentation or support would be needed to ensure that technology capabilities are implemented in ways that effectively improve clinical workflows?

Vendor and payer adoption of specific standards must be a prerequisite for any required adoption by physicians, as physicians are dependent on their EHR vendors to provide the functionality and on payers to adopt the standards so they can be used to fulfill prior authorization requirements. Given the significant burden prior authorizations currently impose on family medicine practices, we expect physicians will be eager to adopt new prior authorization standards as long as they enhance efficiency and reduce care delays. We note that, if electronic prior authorization is mandated for clinicians, the incentives for CEHRT vendors and payers to implement solutions that are efficient and effective for physicians and other health care professionals will be dramatically diminished. As a result, the AAFP recommends against mandating the use of electronic prior authorization standards by clinicians.

Additionally, vendors will charge physician practices for updating EHR systems to implement new prior authorization standards. The cost of these updates could hinder adoption of and willingness to use new standards. Therefore, HHS should prioritize reducing the cost of adoption to physician practices.

What estimates can providers share about the cost and time (in hours) associated with adopting and implementing electronic prior authorization functionality as part of care delivery processes?

Adopting and implementing electronic prior authorization functionality as part of regular care delivery goes beyond just purchasing and implementing new technology. Practices must factor in additional costs and time to conduct trainings with staff, increase staff levels or staff compensation to meet these standards and requirements, and dedicate time to program support and troubleshooting, among other items. Physicians already spend almost two business days per week dealing with prior authorization on top of regular patient care, and implementation of new functionality will intensify that burden as practices adjust to new workflows. To optimize the adoption of future standards, we urge ONC to minimize the costs that can be passed onto physician practices when they are updating their EHRs to implement new prior authorization standards.
Thank you for the opportunity to provide comments on the request for information. The AAFP stands ready to partner with HHS to streamline and reform prior authorization. Should you have any questions or wish to discuss our comments further, please contact Meredith Yinger, Manager, Regulatory Affairs, at myinger@aafp.org or 202-235-5126.

Sincerely,

Ada D. Stewart, MD, FAAFP
Board Chair, American Academy of Family Physicians