



March 25, 2022

Micky Tripathi, Ph.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street SW
Washington, DC 20201

Re: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria
Request for Information

Dear National Coordinator Tripathi:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the National Coordinator for Health Information Technology's (ONC) request for information regarding electronic prior authorization standards, implementation specifications, and certification criteria. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP supports the adoption of additional standards, implementation specifications, and certification criteria as part of the Certification Program to ensure that technology is available to physicians and their staff for the automated, electronic completion of prior authorization tasks. However, it is important for stakeholders within health care to be united on how to reduce prior authorization burden, including vendors being willing to incorporate new functionalities into their systems and organizations having the necessary resources and choosing to implement those functionalities in a timely way. ACP believes standardizing the process and procedures for reporting electronic prior authorization criteria could potentially ease a major source of administrative burden for clinicians who currently use different data, formats, and procedures to process prior authorization requests that vary based on a patient's health plan. The current process often creates unnecessary or duplicative tasks on the part of the clinician and ultimately takes time away from providing high-value patient care.

Additionally, a practical and helpful next step in improving electronic prior authorization processes for physicians and their staff would be to require vendors, pharmacy benefit managers, and durable medical equipment (DME) carriers to supply formularies at no cost from the outset, which would hopefully circumvent many prior authorization requests. Furthermore, there may be situations where prior authorization requests are unnecessary and could be eliminated altogether, and we urge ONC and HHS to consider instances where the drain on resources from prior authorization can be avoided in the first place. For example, patients on state assistance programs may have no flexibility in terms of which DME they can get, yet clinicians must still complete the prior authorization process for the DME. The prior authorization is then denied, and the reason for denial presented to clinicians is simply "on state assistance, does not qualify." This process only creates administrative burdens for clinicians and their staff and wastes precious time and health care resources. Ideally, the need for prior authorization would

decrease as the health care system continues to evolve to a more widespread value-based payment system, particularly for clinicians participating in risk-bearing alternative payment models. A great first step toward this ideal would be for ONC, CMS, private payers, and EHR vendors to accept the same clinical definitions for data elements and report formats. All stakeholders must work together and with the goal of transparency so that health IT can be programmed to generate and send the necessary prior authorization criteria automatically.

The College urges ONC to foster and incentivize the development of systems that would provide timely responses to physicians from payers regarding electronic prior authorization. For example, automated or semi-automated reviews of DME requests could reduce time spent on these requests, minimizing delays in patient care. There is a need for real-time decisions with respect to prior authorization requests, as receiving a response to a prior authorization request after the patient has left the office causes additional, unnecessary administrative work outside of the patient visit and can delay appropriate treatment for the patient. A timely response at the point of care is integral to streamlining this process. Additionally, ONC should require that if the payer’s response is a negative coverage decision, the response should be required to include precisely what documentation is needed from the clinician in order for the payer to reverse the decision. This is similar to step therapy and nonmedical drug switching policies, which can also monopolize time and practice resources with lengthy appeal and exception request policies that can further delay patients receiving effective medications. The administrative burden of maintaining insurer preferred drug lists and time spent requesting prior authorizations [is estimated to cost \\$1,569 per physician per year](#) for statins and antihypertensives. For electronic prior authorization to be meaningfully useful to the clinician, decrease burden, and improve patient care, the response from the payer must contain actionable information so the clinician can either easily provide any missing information or provide a clinically appropriate alternative to their initial prescription.

Certified Health IT Functionality	
Do the functional capabilities described above 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 (please cite the reason they should be excluded) or should ONC focus on a more limited set of functional capabilities for certified Health IT Modules than those described above?	
Preamble FR Citation: 87 FR 3480	Specific questions in preamble? <i>Yes</i>
<p>Public Comment Field:</p> <p>While the functional capabilities described will be helpful, the benefits of electronic prior authorization functionality will not be realized until vendors choose to make the functionality available and organizations choose to adopt the functionality. ACP encourages ONC to consider how current laws and regulations could be best utilized to impact clinical workflow and contribute to the reduction of clinical burden. As a leading partner in stakeholder discussions, ONC is strategically positioned to communicate effectively with vendors on these issues and motivate them to make these functionalities available through practical mechanisms and at affordable prices. Under-resourced health systems and practices currently suffer the most in terms of prior authorization burden, and they</p>	

are also the least likely to be able to afford the implementation expenses of electronic prior authorization. Therefore, having certified electronic prior authorization functionality is not enough; to meaningfully reduce prior authorization burden, the products and functionality must also be affordable to implement. Ideally, these functionalities would be incorporated into regularly scheduled EHR updates and system upgrades that are part of existing contracts.

Finally, functionality offered by EHRs must be better than, and not equal to, the currently utilized systems for prior authorization, such as online portals and 1-800 lines. Functionality must be easier for physicians and practices to navigate in order to truly mitigate burdens associated with the prior authorization process.

Certified Health IT Functionality

Should ONC adopt a certification criterion for prior authorization that accounts for the full, HIPAA compliant workflow for prior authorization transactions including translation from FHIR to the X12 standard? Or should ONC adopt certification criteria that include only the workflows up to the point of translation? What ongoing challenges will stakeholders face if there is a need to translate between HIPAA-adopted standards and other standards that have only been adopted under the Certification Program used to support prior authorization transactions? How should HHS address alignment between standards adopted for HIPAA transactions and standards adopted under the Certification Program?

Preamble FR Citation: 87 FR 3480

Specific questions in preamble? *Yes*

Public Comment Field:

ACP believes ONC should adopt a single set of certification criteria for prior authorization that accounts for the full, HIPAA-compliant workflow for prior authorization transactions. The College acknowledges that harmonization of this nature would involve compromises for stakeholders and could be expensive and time-consuming for health care systems to implement initially; however, harmonization would save physicians and their staff a significant amount of duplicative work in the long-term. Maintaining two sets of standards would require physicians and their care teams to gather enough patient information to be able to satisfy either system's requirements, making it inherently more burdensome. For frontline physicians who are already facing burnout and staff shortages, investing now in a single harmonious standard would be the best option for preventing the long-term challenges and inefficiencies of having to translate between and satisfy multiple sets of standards. Our members' experiences reflect what has been proven repeatedly: prior authorization is a significant drain on the entire health care system. ACP believes there being a single set of certification criterion for prior authorization has the potential to reduce unnecessary delays in patient care. To achieve meaningful harmonization, stakeholders would have to agree on necessary functionality requirements, discuss implementation implications for health systems and practices, and be willing to harmonize their various systems on an agreed-upon timeline.

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?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

ACP appreciates ONC's commitment to expediting patients' access to necessary prescription drugs and its recognition of the burden associated with prior authorization. Physicians and patients need data and tools at their fingertips in order to properly evaluate treatment options and make choices – and current health IT systems and decision support tools are not sufficient to meet these needs. A [December 2021 AMA survey](#) of physicians found that 93% reported prior authorization resulted in care delays for their patients and had a negative impact on clinical outcomes, with 34% indicating prior authorization led to a serious adverse event for their patients. (N=1,004 practicing physicians; 40% primary care physicians, 60% specialists.)

An [October 2020 survey](#) conducted by America's Health Insurance Plans (AHIP) and independent nonprofit analytics firm RTI International found that electronic prior authorization, as compared to manual performance of prior authorization processes, reduces the prior authorization request-to-decision time by about 69% (from 18.7 hours to 5.7 hours). For clinicians who use electronic prior authorization for the majority of their patients, nearly three-quarters (71%) reported that the time to care was faster than it had previously been.

Furthermore, a 2020 [publication](#) in the *Journal of the American Pharmacists Association* indicates that electronic prior authorization increased efficiency and decreased turnaround time of prior authorization processing in a centralized prior authorization department of a health care system, resulting in patients being able to receive medications and start therapy sooner. According to the analysis, the health care system experienced a 25% increase in the number of prior authorizations processed per month by a single, full-time prior authorization coordinator and a 62% reduction in the prior authorization turnaround time.

Impact on Providers

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?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

The College appreciates all efforts to reduce health IT-related burden for physicians and their support staff. ACP wishes to emphasize, however, the importance of decreasing physician-specific health IT burdens, which electronic prior authorization functionality would not necessarily achieve. While overall levels of burden for internal medicine practices would likely decrease alongside increasing electronic prior authorization capabilities, most of this burden reduction would be felt by support staff, not

physicians themselves. With workforce shortages and other challenges exacerbated by the COVID-19 pandemic, physician burden has spiraled beyond crisis levels, and reducing physician burden is among the College's highest priorities.

Critically, the level of burden reduction for clinicians will be largely dependent on how resourced a practice is. In small practices that are less likely to have support staff, prior authorization work falls directly on the physician and overburdens them, leading to shortages of physicians in rural and economically depressed areas. In larger practices, while support staff can take on much of the prior authorization work, physicians must still be involved in preparatory work. If electronic prior authorization capabilities could extract more of the initial required data elements from the EHR, it would markedly decrease some of the physician-specific prior authorization burdens, which would benefit all practices regardless of size or staff bandwidth.

One example of a prior authorization burden that is addressable through health IT arises from having different formularies for drugs in the same drug class. Physicians receive excessive, unnecessary prior authorization requests for medications that are in the same drug class as an original prescription but have different formularies. These requests currently require practices to be connected to a pharmacy benefit manager, causing an unnecessary time-sink for physicians and staff. This is similar to known issues in step therapy and nonmedical drug switching, and other cost-curbing formulary designs that can also undermine a physician's ability to provide care. Step therapy and nonmedical drug switching have been shown to delay or inhibit access to effective treatments and put patient safety at risk by [increasing the risk for hospitalizations and other adverse health events](#). To address this issue, it is imperative that electronic prior authorization be separate from pharmacy benefit information, and that this be made a standard for all certified EHR systems. Appropriately integrating formularies into EHRs would help to resolve this issue. We therefore urge ONC to add protocols to the certification criteria for health IT that would separate electronic prior authorization from pharmacy benefit information in order to address this specific cause of burden.

Another problem associated with prior authorizations for durable medical equipment is that vendors often send paperwork for physicians or their staff to complete. To further alleviate burden associated with prior authorization, vendors must not only be required to incorporate electronic prior authorization capabilities into EHRs for clinician use but must also be required to utilize these capabilities themselves when working with practices.

We encourage ONC to incentivize vendors to incorporate electronic prior authorization capabilities into certified health IT by fostering the development of systems that could be affordably implemented into existing workflows and would provide timely responses critical to patient care to physicians. Barriers to electronic prior authorization include EHR vendors' willingness to incorporate electronic prior authorization capabilities into their EHR systems. In the past, excellent standards and capabilities have previously been developed but have not been implemented into EHR systems. ONC must incorporate these standards and capabilities into its certification criteria and further incentivize their incorporation into EHR systems.

For these reasons, the College believes that sustaining the nation's primary care workforce requires taking immediate meaningful actions to decrease physician-specific prior authorization burdens. While increasing electronic prior authorization capabilities within certified health IT is a noble goal, the College insists that larger-scale conversations are needed about the root causes of prior authorization requests, including why physicians receive so many of these requests to begin with and how prior authorization guidance could be updated to alleviate the problem of excessive requests. ACP appreciates the opportunity to be involved in these discussions and welcomes ONC to inform us of

additional ways we can be involved in moving this conversation forward and contributing to meaningful change.

Impact on Providers

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?

Preamble FR Citation: 87 FR 3481

Specific questions in preamble? *Yes*

Public Comment Field:

While data about the average costs of implementing electronic prior authorization is not available, several recent analyses have shown that the cost and time savings associated with implementation are significant. ACP member experiences with electronic prior authorization reflect the same reduction in burden and cost – particularly members who live in states where electronic prior authorization has been legally required for several years.

The [October 2020 AHIP/RTI survey](#) referenced above found that more than half (54%) of clinicians who use electronic prior authorization for the majority of their patients reported a decrease in phone calls and faxes (58%); similarly, 62% reported spending less time on phone calls, and 63% reported spending less time on faxes. (N=309; 74% clinicians (“provider” or nurse), 26% other (medical assistant, authorization specialist, front office staff, or other role).)

A [December 2021 AMA survey](#) of physicians found that 88% described the burden associated with prior authorization as high or extremely high. This same survey found that on average, 40% of physicians have staff who work exclusively on PA. (N=1,004 practicing physicians; 40% primary care physicians, 60% specialists.)

According to the [2019 CAQH Index](#), “While spending on prior authorization constitutes only two percent of the overall medical industry transaction spend (\$631 million), prior authorization is the most costly, time-consuming administrative transaction for providers.” Results of this analysis suggest that the medical industry could save \$454 million annually by transitioning to fully electronic prior authorization transactions, with the majority of these potential savings (\$355 million) attributed to physicians. The CAQH analysis also shows that on average, electronic prior authorization can reduce the time per transaction from 21 minutes to 4 minutes and the clinician’s cost from \$10.92 to \$1.88 per transaction.

Thank you for this opportunity to comment on ONC’s request for information regarding electronic prior authorization standards, implementation specifications, and certification criteria. ACP believes the availability of electronic prior authorization may help promote access to timely care and treatment for patients, while also reducing administrative burden and supporting physicians in their ability to deliver innovative care. Potential changes need to be carefully developed, with impacts on clinical workflow being directly measurable, to ensure that innovations are truly reducing burden for physicians and their staff. We encourage ONC to further study the root of prior authorization requests and consider

instances where the drain on resources from prior authorization can be avoided from the outset. ACP is committed to the ongoing collaborations and discussions necessary to ensure a positive outcome for all stakeholders. We look forward to continuing this work of pursuing a more efficient, equitable, and transparent health care system with ONC, CMS, medical societies, patient advocacy groups, private payers, and EHR vendors. The College appreciates the opportunity to offer our feedback and looks forward to continuing to work with ONC to implement policies that support and improve the practice of internal medicine. Please contact Brian Outland, Director of Regulatory Affairs for ACP, at boutland@acponline.org or (202) 261-4544 with comments or questions about the content of this letter.

Sincerely,

A handwritten signature in blue ink, appearing to read 'ZAR', with a long horizontal flourish extending to the right.

Zeshan A. Rajput, MD, MS
Chair, Medical Informatics Committee
American College of Physicians