

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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Mickey Tripathi, PhD, MPP
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

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

Dear Dr. Tripathi:

The American Society for Radiation Oncology¹ (ASTRO) appreciates the opportunity to provide written comments on the "Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria" as published in the Federal Register on January 24, 2022. CMS' recognition that prior authorization has become a significant burden and barrier to providing high quality, efficient patient care is appreciated. Let's be clear: health plans are shamelessly abusing the prior authorization process to manufacture delays and denials, so action in this area is critical.

ASTRO endorses professionally developed and vetted clinical practice guidelines, appropriateness of care criteria, and consensus-based model policies developed in a transparent manner with peer review and input as a foundation for clinical decision making. However, we are opposed to restrictive prior authorization practices that oversimplify the process of individual patient management and subvert the physician-patient decision-making process.

In this letter, ASTRO seeks to provide feedback on the requests for information that will impact our membership and the patients they serve. We appreciate CMS' focus on improving interoperability and data exchange between payers, third-party applications, and healthcare providers through the establishment of prior authorization standards, implementation specifications and certification criteria. Below are responses to the questions posed to the provider community:

¹ ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists, and social workers. They treat more than one million people living with cancer each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

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?

ASTRO appreciates CMS' interest in improving prior authorization, as radiation oncologists and people living with cancer have been severely affected by prior authorization's unnecessary burdens and interference in care decisions. A recent ASTRO Prior Authorization survey found that 63 percent of respondents said that they or their practice had to hire additional staff to manage the prior authorization process. Additionally, almost 70% of respondents stated that the burden of prior authorization has increased since the onset of the COVID-19 pandemic. Action must be taken to curb the abusive practice that prior authorization has become, while still ensuring appropriate access to high quality patient care. We believe that should electronic capabilities become available in CEHRT, it is likely to reduce the burden of the current onerous process. Adoption and implementation of interoperable electronic prior authorization capabilities will require concise, appropriate and user-friendly electronic forms and software.

According to the AMA 2021 Prior Authorization physician survey, physicians and their staff spend an average of 13 hours per week completing prior authorizations, nearly two whole business days, and 40% of physicians surveyed have staff that work exclusively on prior authorizations. To apply prior authorization without adding to provider burden, ASTRO recommends that CMS align prior authorization requirements with the Consensus Statement on Improving the Prior Authorization Process developed by the American Medical Association (AMA), state and specialty medical societies, national provider associations, and patient representatives. This collaborative effort identified the most common provider and patient prior authorization concerns and developed a set of 21 principles addressing these issues. From these principles, ASTRO agrees that industry-wide adoption of electronic prior authorization transactions and national standards for the electronic exchange of clinical documents will improve process efficiencies, reduce time to treatment and reduce administrative burden associated with prior authorization.

To what degree are health care providers likely to use these new capabilities across their patient panels? Will additional incentives or requirements be needed to ensure healthcare providers effectively 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?

Radiation oncology professionals are extremely likely to utilize a streamlined, electronic prior authorization process to reduce the burden and staff overhead needed in the current process. However, the requirements for prior authorization in cancer treatment vary widely depending on the payer, which creates confusion and adds significantly to the burden of data collection. In addition, and specific to those patients receiving radiation therapy, there is a lack consistent interoperability between radiation oncology treatment planning systems, oncology information systems, and enterprise electronic health records. This can result in a fragmented view of treatment, while the lack of consistency results in massive variability. Requiring standardization of needed information from payers and the use of standards in the API IGs will facilitate more accurate, consistent and straightforward transfer of health data. ASTRO supports the release of new prior authorization requirements through the CMS Conditions of Participation (CoPs) and Conditions for Coverage (CfCs).

As for incentives, CMS has previously requested information on the addition of an improvement activity (IA) for the Merit-Based Incentive Payment System (MIPS) to encourage clinicians to use electronic prior authorization solutions. However, IA is not the right category for inclusion of this metric. The proposed

Payer APIs are developed and maintained by external vendors and should be measured in the same way as EHRs and other information systems utilized in a clinical setting. ASTRO recommends that electronic prior authorization use be measured in the Promoting Interoperability (PI) performance category. The inclusion of the measure in this category, instead of IA, bundles all technology together in one performance category and provides CMS with a complete view of availability and adoption. It also makes the measurement mandatory, as opposed to an option in the IA performance category. In addition, the action being measured is very similar to health information exchange (HIE), clinical data exchange and provider to patient exchange measures already present in the PI category.

The prior authorization measures should include a ramp-up period, similar to the e-prescribing measures, to allow for practices changes. It should be structured like the HIE requirements to measure both the sending and receiving of the essential information. Additionally, not all vendors will develop this technology in a timely manner and the onus should not be on the clinicians, nor will this apply to all clinician types. Exemptions and appropriate measure re-weighting should be made available.

Clinicians will be eager to adopt electronic prior authorization if the technology reduces administrative burden, does not add to their costs, and increases the amount of time they are able to spend with patients. This proposed electronic transfer has the potential to do both; however, the true success is dependent on the presence and utilization of standardized data. As previously discussed, current data utilized in prior authorization forms are not standardized and therefore not electronically capturable. This means that while the form would be submitted electronically, the information would still be entered manually, which does not provide any relief for over-burdened clinicians. ASTRO is working closely with CodeX, a member driven HL7 FHIR accelerator to enable FHIR-based interoperability that will drive improvements for the most important challenges in patient healthcare. CodeX members are integrating and testing the mCODE (minimal Common Oncology Data Elements) FHIR implementation guide within use cases to create new workflows to support better cancer care. In particular, the CodeX Prior Authorization in Oncology use case has begun work to interoperate prior authorization for breast and prostate cancer and is exploring the use of the FHIR DaVinci Implementation Guides with mCODE to facilitate an expedited, automated, and integrated electronic prior authorization process based on standards. CMS should support standards development work like this for all of medicine, but mostly for specialties that are not covered by large initiatives which are frequently focused on primary care medicine. CMS should provide funding opportunities for organizations that are working in this area to support data availability and liquidity throughout healthcare. This will not only encourage prior authorization data transfer, but also other data relevant to care coordination, patient safety and shared decision making.

Finally, in previous regulatory notices CMS has indicated an interest in pursuing gold carding programs that help alleviate prior authorization burden and encourages payers to adopt such programs. ASTRO recommends that CMS consider requiring payers to allow providers with high rates of approvals over a specific time to be exempt from prior authorization requirements when performing treatments considered standard of care. Payers and vendors should be required to consult scientifically accepted guidelines to determine standard of care, rather than the current practice that involves selectively citing sources and guidelines as part of the denial process. Creating a gold-card program and standardizing denial rationale will reduce the time that providers and patients spend anxiously waiting on prior authorization decisions.

If we were to adopt certification criteria referencing the base standard and then update those criteria to integrate implementation specifications in the future, how should these integrations be handled? When and how should the existing systems be replaced? All at once, or as a series of transitional steps?

Adoption should be incremental so that testing can be used to build out examples of how to leverage these emerging guides to solve the complex challenges in oncology prior authorization.

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?

In every recent ASTRO Annual Member survey, radiation oncologists named prior authorization as the greatest challenge facing the field. According to surveys, 93% of radiation oncologists said that their patients experience delays in treatment, 31% of whom report average delays of more than five days, which is a full week of standard radiation treatments. This is cause for alarm given research links each week of delay in starting cancer therapy with a 1.2% to 3.2% increased risk of death.²

The most important issue with respect to prior authorization that CMS should consider is the impact on patients. More than seven in 10 radiation oncologists (73%) surveyed said their patients regularly express concern about the delay caused by prior authorization, and 32% of radiation oncologists were forced to use a different therapy for a substantial number of their patients due to prior authorization delays. Additionally, 82% reported that difficulties related to the PA process at least sometimes led to treatment abandonment altogether, while 34% of physicians report that PA has led to a serious adverse event for a patient in their care. Below are excerpts from physician responses to the ASTRO prior authorization survey that demonstrate the impact on patients:

- For many of my patients the prior authorization process adds significant stress and concerns over financial liabilities associated with treatment. When an initial submission is denied or delayed, and a peer-to-peer consultation is requested this adds to the stress level. In these increasingly frequent instances, the authorization is not obtained for several days and can even exceed a week. Denials for a particular service are a most traumatic experiences and I had several patients break down in tears fearing that they would now have to receive an inferior treatment.
- In some situations, patients with severe acute problems such as obstructive tumors, painful tumors, rapid review still is multiple days. Certainly, this can lead to patients not overcoming a severe process and [instead] dying from it. However, in addition, this can leave patients with very severe symptoms while waiting for their treatment authorization to occur. The system is made to put off treatment for days at a time, which is very unfortunate. It is not right, it is inhumane.
- This can be extremely negative from the psychological point of view. Patients are very anxious to get [treatment] started, and some have even had panic attacks during this process. *It places stress on [radiation oncologists] to get multiple plans done quickly rushing an already complicated process.* There is no transparency or effective way to expedite treatment.

CMS must take these actions and more to put an end to restrictive prior authorization practices that oversimplify the process of individual patient care management and abrogate the professional and personal judgments of physicians and patients.

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?

In the latest Council for Affordable Quality Healthcare (CAQC) index, it is estimated that providers spent a total of \$594 million on prior authorization in 2021, with a cost savings opportunity of \$437 million if prior authorization was to become 100% electronic among all payers and medical plans. In just the

² https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0213209

radiation oncology field, a recent study published in the Journal of Clinical Oncology showed that compensation costs for treatment related prior authorization exceeded \$40 million for academic radiation oncology centers alone. Clinics are forced to absorb those costs into their overhead, and it takes away time and money that could be used to assist patients.

Additionally, 44 percent of ASTRO survey respondents said that their prior authorization peer-to-peer reviews are not typically conducted by a radiation oncologist. The purpose of prior authorization is to ensure patients are being treated in the most appropriate and efficient way possible when equivalent choices are available, and thus prevent overutilization of medical services. Unless a review is performed by a radiation oncologist, it is impossible for the reviewer to determine if the treatment is efficient and appropriate. This is additional physician staff time being spent on prior authorization that is of no benefit to the provider or patient.

ASTRO has previously shared our concerns that third-party vendors will use regulatorily-required updates as an opportunity to generate additional charges and fees for their products. These excess charges are a financial burden for many practices, especially for small and rural practices, who often find these costs prohibitive. ASTRO recommends that the CMS and ONC carefully consider the downstream financial impact of new requirements and whether it may be appropriate to set limits on the fees that vendors can charge for their technology upgrades related to any future updates. Likewise, since payers are requiring prior authorization, they should bear the full costs associated with electronic prior authorization and providers should be completely held harmless. Unfunded mandates undercut the benefits of making healthcare data more readily available and reduces funds that should be allocated toward patient care.

Thank you for the opportunity to comment on this proposed rule. We look forward to continued dialogue with CMS officials. Should you have any questions on the items addressed in this comment letter, please contact Emilio Beatley, Health Policy Coordinator (703) 839-7360 or via email at Emilio.Beatley@astro.org.

Sincerely,

Laura I. Thevenot Chief Executive Officer

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Enclosed: Prior Authorization and Cancer Patient Care, Nationwide Physician Survey Executive Summary, April 2019