

December 24, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9123-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically: <http://www.regulations.gov>

Re: CMS-9123-P: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications

Dear Administrator Verma:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the “Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes; etc.” proposed rule as published in the Federal Register on December 18, 2020. CMS’ recognition that prior authorization has become a significant burden and barrier to providing high quality, efficient patient care is appreciated. 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. A recent ASTRO survey demonstrated that for almost 70% of respondents, 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.

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 cancer patients 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.

In this letter, ASTRO seeks to provide feedback on the proposals and 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. Overall, ASTRO supports the intent of the proposed rule, as we believe that it is a step in reducing the burden of prior authorization processes for providers and affording greater transparency for providers and Medicaid and Children's Health Insurance Plans (CHIP) patients alike. **We strongly encourage CMS to apply prior authorization reforms to Medicare Advantage plans to help alleviate undue hardship.**

Patient Access API

ASTRO agrees that standardization of Patient Access Application Programming Interface (API) Implementation Guides (IGs) that are utilized by payers, are necessary to facilitate data exchange. The current Electronic Health Record (EHR) landscape illustrates that interoperability is indeed interpreted differently by payers and third-party vendors, and this requirement will help ensure greater interoperability.

CMS also proposes that prior authorization decision making criteria be made available to patients through the Patient Access API, allowing them a better understanding of the prior authorization process and how it directly impacts their care. ASTRO supports this proposal, noting that currently, providers are often left to explain a prior authorization denial to a patient, and deal with the corresponding fallout of a decision they did not make. In a 2019 survey¹, 70 percent of ASTRO members stated their patients regularly express concerns to them about delays caused by prior authorization. Including the date of prior authorization approval, the date the authorization ends, and the units and services approved in the Patient Access API will help alleviate some patient concerns and empower them to participate as an active agent in their care delivery and coverage determination process. Sharing this same information via the Provider Access API, upon the provider's request, facilitates more open discussions about the prior authorization process between patients and providers.

Provider Access APIs

ASTRO appreciates the acknowledgement that data reporting poses a significant burden on clinicians and takes significant time away from treating patients; reporting into additional systems only increases this burden. We agree that adoption of Provider Access APIs and Fast Healthcare Interoperability Resources (FHIR) standards can address this issue by requiring uniformity of data standards. The majority of cancer care data lacks a standardized language, so at times even data exchanges between cancer specialists working with the same third-party vendor product does not occur. Data standardization is the crux of interoperability. ASTRO looks forward to working toward this goal with CMS.

Additionally, CMS recognizes that clinicians often are not provided with information regarding authorizations other providers have requested or received for patients they share. CMS proposes

¹<https://www.astro.org/ASTRO/media/ASTRO/News%20and%20Publications/PDFs/ASTROPriorAuthorizationPhysician-SurveyBrief.pdf>

to require payers to share pending and active authorization decisions with other providers and other payers involved in a patient's care. **ASTRO agrees that payers should be required to share this information. Clinicians cannot treat the whole patient when data that directly impacts the coordination and continuity of care is not provided to them.**

Documentation and Prior Authorization Burden Reduction through APIs

CMS is proposing several policies to help alleviate the burden that prior authorization causes for providers and patients alike. Varied payer policies and practice workflow issues cause the prior authorization process to be a burden for both providers and payers, leading to burnout for providers and risking patient health with care delays. ASTRO agrees that the Drug Registration and Listing System (DRLS) API will help streamline prior authorization submissions by allowing providers to more easily and accurately determine if prior authorization is required, and what documentation should accompany a prior authorization request. **Standardization of the information will lessen the burden for providers, beneficiaries, and payers by decreasing the amount of time that is wasted on incorrect or incomplete prior authorization requests.**

CMS also proposes that State and Medicaid managed care plans be required to provide prior authorization decision notice within a specified timeframe, with expedited decisions being made and communicated in 72 hours and standard decisions be made and communicated in seven calendar days. ASTRO supports this proposal, as many delays in care for cancer patients are due to onerous prior authorization reviews. In ASTRO's 2019 prior authorization survey, 93 percent of radiation oncologists noted their patients experience delays in treatment, with 31 percent reporting average delays of more than five days. This is cause for great concern, when research demonstrates a 1.2 to 3.2 percent increased risk of death with each week of delay in starting cancer treatment.² Therefore, we encourage CMS to consider updating the time frame for expedited decisions from 72 to 48 hours.

Impacted payers would also be required to publicly report prior authorization metrics to stabilize the prior authorization process and improve patient access to timely, necessary care. This is an important step in aligning with the *Consensus Statement on Improving the Prior Authorization Process*³, as is standardization of prior authorization forms. ASTRO agrees with these initiatives.

According to the proposed rule, CMS believes that gold-carding programs could 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 which involves selectively citing sources and guidelines as part of the denial process. **Creating a gold-card**

² Khorana AA, Tullio K, Elson P, Pennell NA, Grobmyer SR, et al. (2019) Correction: Time to initial cancer treatment in the United States and association with survival over time: An observational study. PLOS ONE 14(4): e0215108. <https://doi.org/10.1371/journal.pone.0215108>.

³<https://www.astro.org/ASTRO/media/ASTRO/Meetings%20and%20Education/PDFs/ADay19/priorauthconsensustatement.pdf>

program and standardizing denial rationale will reduce the time that providers and patients spend waiting on prior authorization decisions.

ASTRO appreciates these policies, as radiation oncologists named prior authorization as the greatest challenge facing the field in both 2018 and 2019. While we appreciate the need to curb services that are not medically necessary, the use of prior authorization has long-resulted in delays in care and eroded the value of physician-patient decision making process.

Payer-to Payer Data Exchange on FHIR

CMS seeks to expand upon the Interoperability and Patient Access final rule (CMS-9115-F) and proposes that impacted payers be required to use FHIR-based APIs for payer-to-payer data exchanges. ASTRO supports CMS' assertion that this requirement will encourage data sharing between impacted payers, therefore improving patient access to their health information.

Under this proposal, payers would be required to exchange claims and encounter data, and report any pending and active prior authorization decisions, at a patient's request. CMS also proposes that impacted payers share claims and encounter data during their annual open enrollment period, or during the first quarter of each year. The HL7 FHIR Bulk specification enables payers to exchange information for multiple patients at once, thus enabling patients to take their health information with them when they enroll with a new payer.

ASTRO appreciates that these proposals are an important step in giving patients rightful access to their own health information. Burdensome prior authorization policies have become a blunt instrument used by private payers and Medicare Advantage plans to prevent patients from accessing care. Transparency of encounter data and prior authorization decisions will lead to better communication between patients and providers and improve continuity of care.

Additionally, the Agency will consider future rulemaking that requires payers to demonstrate that they have reviewed previous plan's prior authorization decisions before requiring patients to begin a new prior authorization process. **ASTRO strongly supports this initiative and agrees that payers should honor a previous payer's active prior authorization decisions, for a specific time frame, when a patient changes payers so they may continue to receive necessary care.** ASTRO looks forward to working with CMS on future rulemaking that curbs harmful prior authorization practices.

Request for Information: Methods for Enabling Patients and Providers to Control Sharing of Health Information

ASTRO appreciates CMS' acknowledgement that many patients and providers would like greater control over the sharing of patient health information. While we support patient autonomy, certain subspecialties, including radiation oncology, are quite technical and could present a challenge for patients attempting to share their health data. We recommend that the API IGs include information regarding applicable medical terminology definitions, the overall prior authorization process, and access to a user guide to assist patients. ASTRO is also concerned that the data necessary for radiation oncology may not be found in the proposed data sets and urges

CMS to include data from other electronic clinical documentation portals (such as treatment planning systems for radiation oncology).

CMS requested feedback regarding how this level of data segmentation might create cost or resource burden for providers. 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 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. These unfunded mandates undercut the benefits of making healthcare data more readily available and intercept funds that should be allocated toward patient care.**

CMS also requested input on how FHIR can be improved. Bi-directional data exchange is necessary for multi-disciplinary treatment and cancer research, but the lack of codified language and standards makes this nearly impossible. Once collected, the data, whether in a registry or other system, can be meaningless without hours of human-curation and aggregation. Many organizations, such as universities and specialty societies, are working on data standards through FHIR standards and other HL7 profiles, but there remains a lack of standardization on simple data elements as demonstrated in the Duke Clinical Research Institute and the Pew Charitable Trusts Registry Data Standards project⁴. This work demonstrated that simple, demographic data elements like patient sex are not uniform. In addition to requiring standardization across APIs, ASTRO encourages CMS, together with the Office of the National Coordinator (ONC), to ensure seamless data integration and exchange for all specialties and subspecialties.

Request for Information: Reducing Burden and Improving Electronic Information Exchange of Prior Authorization

CMS believes that utilization of electronic prior authorization will reduce burden and improve care, and therefore requests information for consideration in future rule making that identifies current barriers that prevent providers from utilizing electronic prior authorization methods.

Current electronic prior authorization methods lack standardization, and specific to those patients receiving radiation therapy, lack interoperability between treatment planning systems, oncology information systems, and electronic health records. This results in a fragmented view of treatment, while the lack of consistency results in massive variability. Requiring standardization through the use of API IGs will facilitate more accurate 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).

Additionally, CMS has requested information on the addition of an improvement activity for the Merit-Based Incentive Payment System (MIPS) to encourage clinicians to use electronic prior

⁴[Registry Data Standards - DCRI](#)

authorization solutions. ASTRO appreciates that CMS is looking for ways to encourage the use of new technologies through paired metrics. Clinician adoption is especially important when the electronic transfer is intended to reduce clinician burden and delays in treatment that are usually caused by the current prior authorization process. If finalized, the electronic transfer and decreased determination deadlines can have a direct impact on care and outcomes for patients with cancer.

The Improvement Activities (IA) category is by far the simplest category for clinicians to measure and report. In the 2020 MIPS performance year, clinicians have 106 activities to choose from and most are reporting the activities that they have done for years. There is currently no incentive to change the reported activities nor is IA 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) 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. 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 similar to 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.

The functionality required for the electronic transfer of data is incumbent on vendors. Most clinicians do not have the knowledge or ability to create the APIs and rely on vendors to develop, test, and incorporate them in their systems. This functionality should be included as part of the CEHRT certification criteria.

Clinicians will be eager to adopt electronic prior authorization if the technology reduces administrative burden 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. 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. **CMS should support standards development 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.**

Request for Information: Reducing the Use of Fax Machines

CMS has requested comment on how the Agency can reduce or eliminate the use of fax technology which precludes true interoperability. Fax machine use is still a consistent part of a radiation oncologist's workflow, largely due to prior authorization practices which require the use of fax transmission. In the aforementioned ASTRO prior authorization survey, one member shared,

“I am routinely told: Approval requests can be obtained "on-line". When I do this, there are questions that do not apply to my cases, and I have to call anyway. Pre-auth paperwork is requested to be sent to a Fax # (often out of date), or even slower: by mail (with a 60-day waiting period for a decision).”

Frequently, practices submit data only to learn that the benefit manager did not receive it or that the information was submitted after an arbitrarily defined deadline. Standardized electronic submission processes will ease the uncertainty, lessen the time spent by providers submitting for prior authorization, and lead to patients receiving the treatment they need.

ASTRO is concerned that the data needed for prior authorization for radiation oncology may not be found in the proposed data sets and encourages CMS to include data from other electronic clinical documentation portals (such as treatment planning systems for radiation oncology). Implementing electronic data exchange and/or APIs would be beneficial to practices only if the interactions between vendors, payers, and physicians are standardized and can meet the specifications required for the specialty.

We urge CMS to consider requiring payers to make portions of APIs available offline, so that provider and patients who lack consistent internet access can upload information at any time and then share it once they have internet connectivity. The current prior authorization submission process centers around the payer and/or third-party vendor. **We strongly urge CMS to consider the resources of Medicaid and CHIP patients and their providers when reducing the use of fax technology. CMS' proposals will be an important start in reorienting prior authorization to better serve Medicaid and CHIP patients, if payers and vendors are required to create systems that are easily accessible.**

Request for Information: Accelerating the Adoption of Standards Related to Social Risk Data

Social risk factors, such as housing instability, food insecurity, and access to care issues, impact patient health outcomes. Noting that effective value-based payment systems allow providers to care for the whole person and address the patient's individual social risk factors, CMS requests input on how to improve the adoption of standards related to social risk data.

Social risk factors are self-reported, making it difficult to quantify and interpret when sharing across provider types and various screening tools. The degree of information captured can vary greatly. There are existing programs that incentivize providers screening for social risk data,

such as Priority Health⁵; CMS should consider emulating such programs. We also recommend CMS define the aspects of care related to social risk factors that Medicaid and CHIP programs consider reimbursable covered services. Specifying this will provide clarity for providers regarding the data they should report, leading to more uniform communication across different specialties and practices. Finally, payers should establish mechanisms to capture this data in the Patient Access API and Provider Access API, greatly increasing the chances that the patient's social risk information will be obtained and incorporated to benefit the patient's 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 Jessica Adams, Health Policy Analyst (703) 839-7396 or via email at Jessica.adams@astro.org.

Sincerely,

A handwritten signature in cursive script that reads "Laura Thevenot".

Laura I. Thevenot
Chief Executive Officer

⁵ <https://www.priorityhealth.com/about-us/for-the-media/news-releases/first-insurer-to-offer-provider-based-incentives-for-sdoh-data>