May 30, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9115-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers [CMS-9115-P, RIN 0938-AT79]

Dear Administrator Verma:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide written comments on the “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Proposed Rule” published in the Federal Register on March 4, 2019.

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.

ASTRO supports patients having transparent, easy access to their health information, and proposals to ease burden on providers. Specifically, we support efforts to reduce the burden caused by prior authorization requirements. We understand that this Proposed Rule focuses largely on patient access to health care data, and we hope CMS expands provider access to data in order to promote quality of care and enhance health care decision making in future rulemaking. Provider access to data is not only essential to treating patients effectively, but is also essential to the provider’s ability to report complete and accurate information to clinical data registries. Therefore, access to data allows registries to fulfill their mission of improving quality of care through the collection, analysis, and benchmarking of data on health care diagnoses, treatments, and outcomes. We understand that this Proposed Rule is only the first phase of
CMS’s policymaking on interoperability and access to health care data, and we look forward to working with CMS on future rulemaking.

**Easing Burden Caused by Prior Authorization**

ASTRO believes that the provisions in this proposed rule are a start at improving efficiency, especially surrounding prior authorization, by providing for electronic platforms where medical records, and other interactions are shared between benefits management companies and physicians. Radiation oncologists report that prior authorization, including onerous requirements from Medicare Advantage Organizations, is one of the biggest challenges facing their practices, regardless of whether they are in private practice or academic practices. Results from a recent ASTRO survey show:

- 44% of radiation oncologists report typically needing prior authorization.
- 63% of respondents have hired staff to handle prior authorization requests.
- 93% of respondents said their patients experienced delays in care as a result of prior authorization.
- 70% of patients express concern to the radiation oncologists over prior authorization delays.
- 44% of respondents stated that peer-to-peer reviews typically are not performed by a radiation oncologist.
- 85% of radiation oncologists report having to generate multiple treatment plans.
- Almost 20% of radiation oncologists report spending more than 10% of their time on prior authorization.

ASTRO members have relayed the following stories to illustrate their frustrations with prior authorization requirements:

- 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).

- This morning I sat on the phone 40 minutes and was dropped once during that wait and had to punch through all the data again. Then when I do get someone on the phone, they ask for all the data again. Then I'm set up for peer to peer review. And they have not yet called when they were supposed to 3 hours ago.

- PET scan delayed 10 days while our staff had to complete several pages of details on the make, model, settings, protocols of our PET scanner.

Cancer patients have been particularly hard hit by this unnecessary burden and interference in care decisions. Radiation Oncology Benefit Managers (ROBMs) require a significant amount of information related to patient care. Frequently, practices submit this data only to learn that the ROBM didn’t 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 patients can receive the treatment they need.

ASTRO is also concerned that the data needed for prior authorization for radiation oncology may not be found in the proposed data sets and urge CMS to include data from other electronic clinical documentation portals (such as treatment planning systems for radiation oncology).

**Interoperability**

ASTRO urges CMS to include using an electronic health record (EHR) to participate in a qualified clinical data registry (QCDR) as an interoperability activity. Allowing providers to receive credit under Promoting Interoperability for interoperability activities would reduce health care provider burden while giving providers the flexibility to pursue innovative applications of health IT. The inclusion of electronic reporting through a QCDR as an interoperability activity is consistent with Congress’s mandate under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) that the Secretary of the Department of Health and Human Services (HHS) encourage the use of QCDRs and certified EHR technology for reporting measures under the Quality performance category of the Merit-based Incentive Payment System (MIPS).

ASTRO encourages CMS to not only look at interoperability from the perspective of different EHRs and electronic clinical documentation portals, but also from the same EHRs and electronic clinical documentation portals. ASTRO members report that often their EHR or electronic clinical documentation portals cannot communicate with the same EHR or electronic clinical documentation portals in a different office, often causing a disruption in care coordination between two providers. This lack of data exchange can also lead to delayed treatment and/or potential patient safety scenarios.

**Center for Medicare and Medicaid Innovation Center Models**

CMS is proposing to use Center for Medicare and Medicaid Innovation Center (Innovation Center) models to test ways to promote interoperability across the healthcare spectrum. ASTRO appreciates the Agency’s interest in testing ways to promote interoperability across the health care spectrum through models tested by the Innovation Center. Current Advanced Alternative Payment Models (APM) require the use of Certified Electronic Health Records Technology (CEHRT) by at least 75 percent of participants within the Advanced APM entity. We urge CMS to ensure that efforts to test interoperability do not conflict or place added burden on the existing Advanced APM requirements for CEHRT. As it stands, there are no opportunities for radiation oncologists to participate in Advanced APMs. ASTRO has been working with the Innovation Center on the development of a radiation oncology APM (RO-APM) that meets Advanced APM status. We are hopeful such a model will come to fruition in the near future. While we are supportive of efforts to improve interoperability, we caution CMS against anything that may make the transition from FFS to value-based payment challenging, particularly for groups just entering the Advanced APM space.
We appreciate the opportunity to comment on this proposed rule. We look forward to continuing to work with CMS on this and other issues affecting the practice of radiation oncology. Should you have any questions, please contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs, at 703-839-7366 or cindy.tomlinson@astro.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

May 30, 2019

Dr. Donald Rucker
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Mary E. Switzer Building, Mail Stop: 7033A
330 C Street SW
Washington, DC 20201


Dear Dr. Rucker:


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.

Overall, ASTRO supports the intent of the proposed rule, as we believe that it will move us toward patient access to their health information, if finalized, and in conjunction with the Centers for Medicare and Medicaid Services (CMS) draft proposed rule for Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers [CMS-9115-P, RIN 0938-AT79].

Permitted Fees
While we appreciate the ONC setting boundaries and recognizing financial limitations of providers, we remain concerned that vendors will find other ways to charge more for their products. Specifically, the ONC is permitting fees for: developing, deploying, and upgrading application programming interface (API) technology, and; recovering costs of supporting API usage for purposes other than patient access, exchange, and use. We are aware that vendors are required to upgrade their products to maintain compliance with federal regulations, requiring significant investment in the products. However, these costs are often passed on directly to physicians. As we have mentioned previously in other comment letters, we are concerned that
vendors will use every new, regulatorily-required update or module 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, which often find these costs prohibitive. ASTRO recommends that the ONC carefully consider the downstream financial impact of new requirements, and how they almost certainly result in increased costs for practices. These unfunded mandates undercut the potential benefits of health IT and remove critical funds that should be targeted toward patient care and must be avoided.

The ONC is proposing to remove, add, and change criteria and standards in the 2015 Edition CEHRT requirements. ASTRO is confused as to why ONC is proposing these changes instead of promulgating new rules for a new edition of CEHRT. We are concerned that CEHRT that is now certified as 2015 Edition would no longer be certified because of these new criteria and standards. ASTRO requests clarification on how changes to 2015 Edition CEHRT will work operationally, and how the ONC will help ease confusion among providers and vendors trying to comply with requirements in quality and payment programs. If the ONC moves forward with these changes, we are concerned that this will be another way for vendors to charge additional fees for compliance. As previously mentioned, charging for every upgrade because of regulatory requirements puts an undue burden on providers, especially those in small and rural practices.

**Patient Safety Organizations**
ONC seeks comment on whether the unqualified protection from data blocking afforded to communications made to patient safety organizations (PSOs) about adverse events, hazards, and other unsafe conditions should be limited. ASTRO, together with the American Association of Physicists in Medicine (AAPM) sponsor RO-ILS: Radiation Oncology Incident Learning System®, which is part of Clarity PSO. RO-ILS is the only medical specialty society-sponsored radiation oncology incident learning system. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. With over 500 facilities enrolled in the program and almost 10,000 events reported to the PSO, RO-ILS has released numerous aggregate reports and published findings in *Practical Radiation Oncology*, a peer-review journal to increase awareness of error-prone processes and possible mitigation strategies, including information about human factors engineering.

ASTRO strongly opposes any limitations on the communications made to a PSO provided they are made under, and in accordance with, the Patient Safety and Quality Improvement Act (PSQIA). PSOs, as defined by the Agency for Healthcare Research and Quality (AHRQ), share the goal of improving the quality and safety of health care delivery; collect and analyze data to identify and reduce the risks and hazards associated with patient care; and create a secure, non-punitive environment through confidentiality and privilege protections. Limiting the ONC’s proposed unqualified protections from data blocking will disincentivize providers from participating in this very important patient safety work and could inadvertently prevent the identification and analysis of patient safety issues related to health IT.

There should be no limit to which information providers can communicate to a PSO. PSOs foster a culture of safety and improve the quality and safety of healthcare delivery, of which health IT
is an integral part. Practices and providers that participate in a PSO are required to set up a Patient Safety Evaluation System (PSES), which is a mechanism for collecting, managing and analyzing information and data for reporting to or by a PSO. Providers make the decision about which information is sent to the PSO and when it is sent. ASTRO is concerned that by allowing health IT vendors the ability to limit what information is shared with a PSO, the ONC is giving the health IT vendors too much influence in this area. Providers must be able to control the reporting of its patient safety data.

ASTRO agrees with the proposed rule that public and patient safety interests outweigh any potential for the disclosure of the IT developer’s intellectual property/trade secrets. The proposed rule also states, “for example, government agencies impose appropriate controls on information they receive mitigating any risk that developers may feel arises from the disclosure of information about their health IT.” Similarly, PSOs are governed by the PSQIA, which requires providers to navigate a complex set of state and federal requirements. Vendors should not be allowed to limit data that may contain information about their equipment, which could be sent to a PSO to further a tradition of incident learning and sharing.

**Information Blocking**
ASTRO appreciates the ONC clearly outlining its proposed exceptions to the information blocking provisions. The exceptions would apply to certain activities that do in fact interfere with the access, exchange, or use of EHI but that may be reasonable and necessary if certain conditions are met. The exceptions are: preventing harm, promoting the privacy of EHI, promoting the security of EHI, recovering costs reasonably incurred, responding to requests that are infeasible, licensing of interoperability elements on reasonable and nondiscriminatory terms, and maintaining and improving health IT performance. We do request clarification on how each of these exceptions will be arbitrated, and request that ONC provide additional examples of actions that may fall within each exception. We are concerned that some of the proposed exceptions will give vendors an opening to charge extra fees, and we request the ONC consider all possible loopholes in its final rule. As mentioned above, the cost of compliance is particularly concerning for small and rural practices. Additionally, we are concerned that the information blocking provisions will allow EHR companies to refuse to share their data with registries or charge their customers or registries excessive fees for this data exchange. We are currently seeing this in practice and some of the exceptions might reinforce current behavior.

**Registries Request for Information**
ASTRO appreciates the acknowledgement that data reporting poses a significant burden on clinicians and takes significant time away from treating patients and reporting into additional systems multiplies the burden drastically. We also appreciate ONCs focus on bi-directional exchange to move systems toward semantic interoperability. While APIs can help in some cases, the true issue is the lack of uniformity in data entry and standards. Currently most cancer care data exist in a foundational level of interoperability, where even data exchanged between cancer specialists working with the same vendor product does not occur. Bi-directional data exchange is necessary for multi-disciplinary treatment and cancer research, but the lack of codified language and standards makes this 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 currently working on data
standards through Fast Healthcare Interoperability Resources (FHIR) standards and other HL7 profiles, but there remains a lack of standardization on simple data elements as shown through the recent Registry Data Standards project from the Duke Clinical Research Institute and the Pew Charitable Trusts. This work showed that simple, demographic data elements like patient sex are not uniform. ASTRO feels that data standardization is the crux of interoperability, and in that vein, is developing a list of required data elements in radiation oncology for use in EHRs, registries, or clinical trials. The public comment period for this list has closed, and we expect it to be finalized by the end of the year. Again, API technology will help, but we encourage ONC to provide resources for organizations seeking to undertake the costly and complicated task of developing common standards where none exist and encouraging use where they do.

**Patient Matching Request for Information**

ASTRO agrees with the ONC that patient matching – the linking of one patient’s data within and across health care providers – is an important component of HIT interoperability, however, we are concerned that the ONC is overlooking the complexity of multi-modal care. For example, ASTRO members report that even if a consulting physician uses the same EHR as the ASTRO member, they often have difficulty communicating electronically, and need to find work-arounds to get patient information from one office to the other. Patient matching certainly can facilitate “improved patient safety, better care coordination, and advanced interoperability” when data from one system aligns with the data from another; however, more work needs to be done to achieve this goal.

We appreciate the opportunity to comment on this proposed rule. We look forward to continuing to work with ONC on this and other issues affecting the practice of radiation oncology. Should you have any questions, please contact Cindy Tomlinson, Senior Manager for Patient Safety and Regulatory Affairs, at 703-839-7366 or cindy.tomlinson@astro.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

Attachment: ASTRO comments on CMS draft Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers [CMS-9115-P, RIN 0938-AT79]