

August 13, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically: RadiationTherapy@cms.hhs.gov

Dear Administrator Brooks-LaSure:

The American Society for Radiation Oncology¹ (ASTRO) is writing to provide comments on the “RO Model Quality Measure and Clinical Data Element (CDE) Collection and Submission Guide” issued for public comment as part of the 2022 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, which included proposed modifications to the radiation oncology alternative payment model or RO Model. We are dismayed by the lack of recognition regarding the challenges associated with collecting this type of data. We urge the Agency to delay the CDE requirements for two years and reconsider some of the more onerous reporting requirements, as well as seek ways to align with existing electronic health record (EHR) and Merit Based Incentive Payment System (MIPS) reporting parameters.

ASTRO has made every possible [effort](#) to engage with the Agency on the development of appropriate data element collection methods, yet key elements are missing that we continue to champion in this comment letter. First, there needs to be alignment with the existing MIPS reporting parameters, so that those practices accustomed to reporting through MIPS can seamlessly transition to the RO Model. Secondly, CMS must recognize the process outline in the Submission Guide is labor-intensive and must, therefore, provide participating practices with the financial resources to satisfy these requirements.

In theory, we understand why CMS wants to collect this data and appreciate the need to use this information to inform future quality measures, which we agree are at a paucity for the specialty. However, the process of doing this through the CDE collection requirements as laid out by the Agency would be daunting for many practices. We request that the Agency consider the following modifications:

- Drop the delivered dose requirement and use prescribed dose

¹ ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the world. 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.

- Provide clarification regarding staging requirements
- Delay the CDE requirements for two-years
- Consolidate the reporting periods into one date – March 31st

Clinical Data Elements

According to the guidance document, CMS is assigning unique numeric identifiers for the collection of anatomic site, lymph nodes, fractions, dose per fraction, total dose, laterality, histology, intent, ISUP grade, Gleason and more. Anatomic target and laterality are included in ICD-10 codes. Reporting this data using distinct codes is duplicative and unnecessary. We are surprised and disagree with many aspects of the Agency's proposal.

COC-centric Regulations. ASTRO is concerned that CMS is requiring RO participants to collect target, dosage, and fractionation data in the same manner as required by facilities accredited by the Commission on Cancer (COC). None of the data currently collected by COC has resulted in any quality measures specific to radiation oncology for any of the included disease sites, it is doubtful that this exercise would yield anything different. Additionally, while ASTRO is a member of the COC and appreciates its leadership in the cancer space, we are surprised by the agency's favoritism in selecting their system as the mandated data model. The COC is a voluntary group of 1,500 hospitals who perform the vast majority of cancer surgeries. This places an additional burden on those radiation oncology practices that are not COC accredited, including freestanding practices. Furthermore, the COC standards related to radiation therapy are minimal, due to the fact that COC is sponsored by the American College of Surgeons, and thus their standards are focused on surgical procedures. Lastly, we will note that several publications^{2,3} have discussed the limitations of radiation therapy data in National Cancer Database (NCDB), underscoring that the COC framework may not be reliable in the realm of radiation oncology.

Dose per fraction (3.2.1.3). On page 18 of the guidance document, CMMI is requesting the actual number of fractions delivered rather than the number of fractions prescribed. Treatment delivery information is cumbersome to extract from treatment planning systems and can report out differently depending on how the treatment was planned. Unlike medical oncology where the treatment plan may vary from the initial prescription with changes based on patient tolerance to treatment, in radiation oncology the difference between the planned dose and the delivered dose is not significant and rarely has any clinical significance. ASTRO thinks the minimal difference between the prescribed dose and the delivered dose does not warrant the time and burden associated with reporting on the delivered dose as it has no clinical impact on patient outcomes. **We strongly urge CME to change this requirement to prescribed dose.**

² Jairam, V., & Park, H. (2019). Strengths and limitations of large databases in lung cancer radiation oncology research. *Translational Lung Cancer Research*, 0, S172-S183. Retrieved from <https://tlcr.amegroups.com/article/view/29070>

³ Yang DX, Khera R, Miccio JA, et al. Prevalence of Missing Data in the National Cancer Database and Association With Overall Survival. *JAMA Netw Open*. 2021;4(3):e211793. doi:10.1001/jamanetworkopen.2021.1793

Cancer Stage (3.3.1). On page 24 of the guidance document, CMMI is requesting the AJCC, T, N and M values that are documented closest to the start of the 90-day episode. Cancer patients have complex medical records with many different staging events on different dates and even different types of staging. In the context of clinical data element reporting, ASTRO urges CMMI to provide additional clarification regarding whether the staging reported is the staging performed prior to the treatment date on the date closest to the date of radiation treatment or staging occurring after the treatment date. Additionally, CMMI should clarify whether the staging reported is clinical staging or pathological staging. If both clinical and pathological staging occur on the same date, and are both required for reporting, should there be a preference for reporting pathological staging over clinical staging?

Mandating manual extraction. As proposed, all CDEs will need to be manually reported utilizing a template provided by CMS. This will take significant time and resources. Freestanding RO Model participants, who unlike voluntary COC hospitals do not have registrars in place to collect this data, will be forced to hire and train staff to interpret and record the various elements in the patient record, and then manually input them correctly into the template. Otherwise, physicians and clinical staff will be required to input this data detracting from patient care. This is coming at a time when practices are still reeling from the financial impact of COVID-19 and many are currently experiencing staffing shortages. According to one RO Model participant, it would take upwards of 20 minutes to input each of the data points for each breast cancer case. Coupled with the CDE reporting requirements for the other disease sites, this presents a significant burden for practices. CMS must allow for greater flexibility in the data submission requirements, recognizing that some practices may not be able to readily extract this data from existing systems and submit it to the Agency.

ASTRO has urged CMS multiple times to find areas of alignment between existing MIPS reporting requirement processes and those associated with the RO Model to reduce reporting burden. We have also encouraged the Agency to collaborate with radiation oncology EHR vendors to identify those elements that can easily be extracted from existing systems before expanding data collection requirements. We are disappointed that these recommendations continue to fall on deaf ears and the Agency would rather pursue a manual input system than engage with stakeholders on establishing a more meaningful process for data collection.

Given the immense expectations laid out in this proposed rule, **ASTRO requests a two-year delay of the CDE reporting.** ASTRO appreciates the reduction from the original RFI; however, the proposed list is still entirely too extensive to expect compliance in less than 4 months. A delay would allow clinicians the appropriate amount of time to develop work flows to consistently document the proposed data elements and provide time for vendors to accommodate the relevant radiation oncology data standards development that is occurring within the mCODE⁴ and CodeX⁵ initiatives. Additionally, time is needed to modify and adopt software for the tasks related to clinical data elements and to clarify gaps and ambiguities in the instructions involving the clinical data element and engage in necessary training. RO

⁴ The Minimal Common Oncology Data Elements (mCODE™) initiative provides both a common data language and an open-source, nonproprietary data model for interconnectivity across systems.

⁵ CodeX (Common Oncology Data Elements eXtensions) is a Member-driven HL7 FHIR Accelerator, building a community to accelerate interoperable data modeling and applications that lead to step-change improvements in cancer patient care and research.

Model participants could still be compliant with quality reporting through the quality measures, if the CDE aspect is delayed.

Quality Measures

Advanced APMs should rely and build upon processes and mechanisms that have already been laid out in MIPS. However, ASTRO is concerned about the proposed data collection and reporting plan associated with the RO Model. Each of the four measures are electronically specified and can be collected and reported by vendor systems. MIPS allows for multiple submission mechanisms, which is why we are surprised to see only one, manual option for the RO Model quality measure reporting. We appreciate that the Agency is providing a simplistic approach so that reporting can be accessible for all included participants; however, in all other quality reporting programs CMS is heralding digital quality measures and the use of FHIR APIs. To ignore this transition to increased interoperability flies in the face of advancing the future of healthcare data collection. ASTRO recommends allowing for multiple collection and reporting mechanisms for the quality measures, beyond the proposed template, to align with current processes in other quality reporting programs and to reduce the enormous burden that the current proposal would add to radiation oncology practices.

Plan of Care for Pain

ASTRO remains concerned about the inclusion of the Oncology: Medical and Radiation – Plan of care for Pain (NQF41 #0383; CMS Quality ID #144) quality measure, particularly given that CMS has decided to remove this measure from the IPPS, HOPPS and MIPS quality reporting programs. It is difficult to understand why this measure continues to be included in the RO Model, despite the Agency's decision that it has no value in the other programs.

In the guidance document, CMS recognizes that #144 was developed as a paired measure with Oncology: Medical and Radiation – Pain Intensity Quantified (NQF #0384; CMS Quality ID #143). The pairing is to determine which patients have pain of any level and then document a plan of care for those patients. The Agency also acknowledges that without the quantification measure, RO Model participants will not be able to ensure a correct denominator population to CMS. While the Agency does not require reporting on #143, it will still need to be quantified and RO Model participants will not receive any acknowledgement through the Aggregate Quality Score (AQS) for collecting this data. The Agency should account for the work involved to collect this data through the AQS.

Reporting Periods and Successful Reporting

CMS is establishing three distinct reporting periods associated with CDE and Quality Measures data reporting. CDEs are reported biannually by July 31 for episodes ending between January 1 and June 30 and by January 31 for episodes ending between July 1 and December 31. Quality measures data must be submitted by March 31 after the end of each performance period. If the AQS is determined one time per year, then why does CMMI need three distinct data reporting periods? The Agency must combine all three reporting periods into one: March 31.

Additionally, successful reporting of CDE's is set at 95% of RO beneficiary episodes completed during the performance year. This threshold is incredibly high and it will be an extreme burden for practices to report data multiple times per year. CMS must consider a gradual requirement that starts at 25% of RO

beneficiary episodes in the first performance period, growing to 75% over the duration of the RO Model demonstration period.

ASTRO appreciates the opportunity to provide input on the RO Model Quality Measure and Clinical Data Element Collection and Submission Guide. Should you have any questions regarding our recommended modifications and concerns, please contact Randi Kudner, Senior Quality Improvement Manager, at RandiKudner@ASTRO.org or 703-286-1664.

Sincerely,

A handwritten signature in black ink that reads "Laura Thevenot". The signature is written in a cursive, flowing style.

Laura I. Thevenot
Chief Executive Officer