ASTRO
TARGETING CANCER CARE

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January 22, 2021

Elizabeth Richter
Acting Administrator, Centers for Medicare and Medicaid Services
The U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Administrator Richter:

On behalf of the American Society for Radiation Oncology (ASTRO), I am writing in response to the revisions made to the Radiation Oncology Alternative Payment Model (RO Model), as described in the 2021 Hospital Outpatient Prospective Payment System (HOPPS) final rule. ASTRO submitted detailed comments and suggestions to the RO Model proposed rule in September 2019, few of which were incorporated into the final rule. ASTRO stands by our comments and continue to believe they represent the best path forward.

ASTRO strongly supports the provisions of the 2020 Year-End COVID-19 Emergency Relief Package that delayed the RO Model implementation date until January 1, 2022. This delay affords us more time to work together to significantly improve the RO Model and address the negative repercussions the Model design will have on cancer patients seeking access to radiation treatment options and new technology.

As we stated previously, ASTRO believes that the RO Model, with modifications, could be a meaningful step for the field of radiation oncology to participate in health care payment reform. ASTRO remains committed to working with the Agency to meet that goal. Our specific goals for the model are the same as those that we articulated in our first set of comments:

1. The RO Model should reward radiation oncologists for participation and performance in quality initiatives that improve the value of health care for patients.

2. The RO Model should ensure fair, predictable payment for the radiation oncologist in both hospital and freestanding cancer clinics to protect cancer patients' access to care in all settings.

3. The RO Model should incentivize the appropriate use of cancer treatments that result in the highest quality of care and best patient outcomes.

The Agency's decision in the 2021 HOPPS final rule to compel practices to participate in a Model that eliminates the possibility of earning an Advanced APM bonus and imposes payment cuts and burdens associated with changing practice operations demonstrates CMS' singular interest in reducing payments via the model. ASTRO's concern regarding the Agency's sole focus on cutting payments is shared by a variety of stakeholder groups who are also equally committed to value-based care transformation. The Health Care Transformation Task Force (HCTTF) stated this concern eloquently in a recent letter[1]:

[1] Meoli, Angela, et al. "Health Care Transformation Task Force letter to President-Elect Joe Biden and Vice President-Elect Kamala Harris." 18 Dec. 2020. https://hcttf.org/wp-content/uploads/2020/12/B-H-Admin-Transition-team-letter-12-20-Final.pdf

> "Rather than prioritizing maximum savings during the model test period, models should be designed to focus on long-term impacts to health care spending and quality with the goal of model expansion."

CMS' current approach to APMs is flawed and must be refocused on improving quality first and foremost.

We strongly agree with bipartisan Congressional leaders that have recognized and seek to correct the model's flaws. Specifically, Members of Congress have called on CMS to modify the RO Model so that it more accurately reflects the goals of improving patient care and establishing rate stability[2]:

> "If designed appropriately, the RO Model can be an excellent opportunity to test bundled payments, modernize Medicare to keep up with clinical advancements, and provide more stability in radiation oncology payments. Our concern is that instead the RO Model, as currently constructed, could impede the original goals of improving health outcome to cancer patients due to the parameters as currently proposed."

By delaying implementation until Jan. 1, 2022, Congress has intentionally created an opportunity for the Agency and radiation oncology community to collaborate on necessary changes. We believe a serious consideration of ASTRO's proposed rule comments, most recently articulated in our November 3, 2020 letter, represents an important first step to getting the model back on track.

Additionally, we want to again raise our concerns regarding the significant fluctuation in the Agency's estimated impact on Medicare fee-for-service (FFS) payments under the RO Model, set forth in the November 30th "Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures; Correction." The "correction" demonstrates that the Agency did not have an accurate appreciation of the financial impact of the RO Model when it was finalized. We believe that revising the financial impact in the correction notice constituted such a substantial change to the model, that the Agency must engage in further notice and rulemaking before it can implement the RO Model.

Finally, we have spent the last several months since the issuance of the RO Model final rule working with practices identified as RO Model participants to help them understand the financial impact the model will have on their practices. This has been made more difficult by the Agency's failure to provide meaningful guidance and information to practices in a transparent manner. We urge CMS to provide the radiation oncology community with access to the data files for 2016-2018 used to determine the National Base Rates, as well as the methodology associated with determining the historical experience and case mix components. As stated above, new rulemaking is required before the RO Model start date. For all interested parties to submit meaningful comments to this rule, CMS must provide all data that it relied upon in proposing any regulatory changes. The complexity of the RO Model warrants the need for greater transparency and data sharing, so that those participating have a complete understanding of the RO Model's ramifications and the opportunity to dispute inaccurate calculations.

Through greater transparency and meaningful collaboration, we can make the RO Model viable and meaningfully transition radiation oncology from FFS to value-based payment. We look forward to

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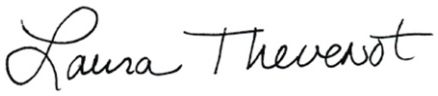
[2] Kelly, Mike, Higgins, Brian, et al. "Members of the United States Congress letter to CMS." 18 Dec. 2020. https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/RadiationOncologyModelLetter.pdf

continued discussions and opportunities to engage with the Agency. If you have any questions, please contact Anne Hubbard, Director of Health Policy at 703-839-7394 or Anne.Hubbard@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer

Enclosure: ASTRO RO Model Comment Letter, November 3, 2020

CC:
Chiquita Brooks-Lasure, Biden Transition Team
Deputy Administrator and Director, CMS Center for Medicare and Medicaid Innovation (CMMI)
Amy Bassano, Deputy Director, CMMI
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November 3, 2020

Alex M. Azar, II, Secretary
Seema Verma, Administrator, Centers for Medicare and Medicaid Services
The U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar and Administrator Verma:

On behalf of the American Society for Radiation Oncology, I am writing to express appreciation for the Agency's decision to delay the implementation of the Radiation Oncology Alternative Payment Model (RO Model) until July 1, 2021. The delay recognizes the significant investment of resources and effort required to operationalize this new payment model during the COVID-19 public health emergency. Critically, the delay also provides an opportunity to collaborate to address the significant concerns in the radiation oncology community on the need to modify the many significant flaws of the RO Model. Specifically, the payment methodology and the burdensome data collection and reporting requirements must be reformed to ensure that practices can successfully participate in the model and achieve its worthy promise and goals. While we recognize the RO Model has been finalized in rulemaking, we cannot let this stand in the way of protecting cancer patients from a model that is certain to limit access to radiation therapy.

Before we explore our recommended urgent reforms, it is important to reiterate that no professional society and medical specialty has pursued an alternatively payment model (APM) more aggressively than ASTRO. In 2015, following the passage of the Medicare Access and CHIP Reauthorization Act (MACRA), we successfully lobbied for passage of the Patient Access and Medicare Protection Act (PAMPA), which initiated CMMI's work on a radiation oncology alternative payment model (ROAPM). In April 2017, after years of internal work and frequent collaboration with CMMI, ASTRO proposed to CMMI an RO APM, from which many concepts in the CMS RO Model can be found. When CMMI needed more time to develop the RO Model, we again lobbied Congress for language in the Bipartisan Budget Act to provide more time for CMMI to issue the proposed RO Model. Despite our significant concerns with the proposed RO Model, we provided more than 40 pages of constructive comments and recommendations, which were echoed by the radiation oncology community, broader health care stakeholders, cancer patients, and numerous bipartisan Congressional leaders.

Given this history, we were shocked and dismayed that most of our recommendations were clearly not considered in the final rule. You will note throughout this document that we are demanding greater transparency and meaningful collaboration with CMS and CMMI officials to secure a more balanced RO Model that provides higher quality and lower costs. We have taken a step backwards because the Agency failed to heed our recommendations and subsequent COVID-19 related warnings. Let's get back on track by using the delay as an opportunity for CMS to work with ASTRO and the broader radiation oncology community to get this model right, so that it truly can be a standard for future models moving forward. Too much is at stake for cancer patients to retreat to our respective corners. We must come together and find common ground.

Payment Methodology Modifications

Discount Factor

ASTRO has been told numerous times by CMS and CMMI officials that significant payment cuts under the model are necessary to satisfy CMMI's statutory authority for conducting such models. ASTRO and our attorneys believe that this is an overly strict reading of the statute that goes well beyond Congressional intent. The statute does not require these excessive cuts, but rather it is the goal of CMS and CMMI leadership to reduce spending to this degree. The statute, in contrast, is clear that a model can continue even if it improves quality but does not cut costs. Furthermore, CMMI can test models that may be "expected" to cut costs, even if they ultimately do not. The RO Model should test whether bundled payments will reduce costs while preserving quality. Instead, CMS is testing whether payment cuts will cut costs. The answer is obvious: Yes. ASTRO is willing to accept the inclusion of a reasonable discount factor in the model to help guarantee Medicare savings, but the levels required by CMS are too high. It is a dramatic and unnecessary overread of the statute to say that a model must have a massive cost reduction mechanism to comply with the law. This strict reading exceeds CMMI's statutory authority and must be rectified.

ASTRO remains extremely disappointed that CMS has moved forward with the application of Discount Factors of more than 3% for both professional component (PC) and technical components (TC). The application of a 3.75% discount off the PC and 4.75% discount off the TC fails to recognize that radiation oncology services rely heavily on the use of advanced technology and equipment that requires a significant financial investment, beyond that of anything else in medicine. Radiation oncology clinics have significantly higher fixed costs compared to other specialties, where the fixed costs are lower due to less reliance on capital-intensive technology and equipment. Practices with significant fixed costs have limited variable costs, and savings are typically generated on reducing variable costs, not fixed costs.

The minimum total capital required to open a freestanding radiation oncology center is approximately $5.5 million. These facilities require an additional minimum $2 million in annual operating and personnel expenses. These significant fixed investments far outweigh the variable costs of operating a radiation oncology clinic and should be given far greater consideration as part of any alternative payment model. While it is important to reduce the cost of care and drive value in healthcare, it is also important to ensure that efforts to generate savings do not cause access to care issues for patients by limiting practices ability to offer state-of-the-art radiation therapy delivered by expert clinical staff. This is particularly important for practices operating in rural areas. We understand the Agency will monitor quality and access throughout the model, but we are certain that these concerns will become reality and patients and practices should not be put at risk. Action must be taken now to prevent this impact on patients.

We have watched closely Administrator Verma's recent remarks on value-based care and have been mindful of the stated direction to increase provider risk and guarantee more Medicare savings. With the RO Model, this approach has gone to extremes. ASTRO has already accepted downside risk and discount factors of 3%, on top of expected savings from realigned incentives in the model, which when combined with mandatory participation guarantee spending reductions. But let's dig deeper, as we

believe CMS is seriously misguided in its overly aggressive approach to secure savings out of radiation oncology, the most cost-effective cancer treatment for Medicare beneficiaries.

Over the last ten years, radiation oncology total allowable charges have represented a declining portion of the total MPFS allowable charges. The overall $47 million or 3% decline in allowable radiation oncology charges between 2010 and 2020, pales in comparison to the overall $15.7 billion or 17% increase in total MPFS allowable charges over the same period.

	Allowable RO* Charges (In Mil)	**Total MPFS Allowable Charges (In Mil)**	**RO as a % of Total MPFS**
2020 (CY)	$1,762	$93,487	1.88%
2019	$1,766	$92,771	1.90%
2018	$1,745	$93,149	1.87%
2017	$1,770	$89,866	1.97%
2016	$1,828	$89,020	2.05%
2015	$1,851	$88,045	2.10%
2014	$1,851	$87,552	2.11%
2013	$2,060	$86,588	2.38%
2012	$2,055	$83,313	2.47%
2011	$2,010	$81,980	2.45%
2010	$1,809	$77,796	2.33%

By comparison, Part D spending for 56 oral anti-cancer drugs amounted to more than $41.4 billion between 2013 and 2017. Increased drug costs accounted for 56% of the $5.9 billion rise in annualized spending, while increased use accounts for 44%.[1] Radiation oncology charges represent only a small fraction of total Medicare expenses and are not a driver for increased Medicare spending. CMS must recognize this reality, by limiting its aggressive pursuit of savings under the RO Model to a more reasonable and balanced level that does not limit access and risk quality.

ASTRO urges that CMS reduce the discount factors to a more reasonable rate of 3 percent or less. This balanced approach will still allow significant savings to accrue to Medicare while avoiding undue financial strain on practices still struggling with revenue declines due to COVID-19.

Trend Factor

A stated purpose of the RO Model is to ensure rate stability throughout the five-year demonstration period. That goal cannot be achieved if the MPFS and/or HOPPS payment systems experience significant shifts from year to year. CMS is proposing a 10.61% cut to the MPFS conversion factor for 2021, which would reduce payments under the MPFS by 6% for practices outside the model, but would also reduce

[1] Seiger,BA, Kira, et al. "Association of Rising Cost and Use of Oral Anticancer Drugs with Medicare Part D Spending From 2013 through 2017." *Journal of the American Medical Association*, vol. 6, no. 1, 2019, pp. 154-156. *JAMA*, doi:10.1001/jamaoncol.2019.4906

the PC payment for each of the disease sites by an estimated average of 3 percent due to the RO Model trend factor.

This significant reduction, in addition to the discount factor and withholds, will put many practices compelled to participate in the RO Model in financial jeopardy. While ASTRO can support the use of a trend factor as an annual update to the base rate, there must be guardrails put in place to prevent significant shifts in payment. **CMS must institute the application of guardrails (i.e. +/- 2%) to the Trend Factor so that shifts in MPFS and HOPPS payment rates do not create significant fluctuations in the Trend Factor from year to year. This provides practices with greater certainty regarding their annual payment rates and softens the impact of shifts that may be taking place in the payment systems outside of the RO Model. Additionally, it still allows the RO Model to recognize changes in payment occurring in the MPFS and HOPPS payment systems.**

National Base Rate

In the RO Model final rule, CMS bases the National Base Rate calculation for the PC and TC on hospital outpatient prospective payment (HOPPS) data from 2016-2018. In response to the proposed rule, ASTRO urged the Agency to modify the National Base Rate to account for Medicare Physician Fee Schedule (MPFS) data as part of the valuation of the PC for each of the disease sites, recognizing the cost of professional services delivered in freestanding settings.

Additionally, ASTRO urged the Agency to establish a separate palliative care episode by removing palliative care data from the PC and TC National Base Rates for each disease site. By removing those cases involving ten or fewer fractions of 3-Dimensional radiation therapy from the calculation of the disease specific PC and TC payment rates, the payment rates more accurately reflect the cost of curative care. Otherwise the PC and TC National Base Rates undervalue curative care.

Finally, ASTRO urged CMS to calculate the payment rates for cervical cancer based on those episodes that demonstrate the delivery of guideline concordant care. As stated in the ASTRO comment letter in response to the proposed rule, the data used to determine the cervical cancer PC and TC payment rates was based on almost 3,000 cases, of which only 600 represented guideline concordant care. ASTRO urged the Agency to modify the payment to recognize the cost associated with guideline concordant care. Frequently, these cases involve transitions of care between physicians and sites of service. We understand that the Agency does not want to "pay twice for the same service" where multiple physicians and multiple sites of service are involved in the delivery of care. The Agency has determined that these services are "duplicate" when in fact they are not. The term "duplicate" is a misnomer applied to the services when it should be applied to the payments. The fact is that services are not being duplicated, but rather there is the potential that payment could be duplicated when the episode payment is issued to the initiating RO Model participant which includes payments associated with services delivered by a second physician or site of service that are separately paid FFS.

While the disease site is the same, in this case cervical cancer, the services delivered are not the same and not duplicate. External beam therapy and brachytherapy are very different services with very different, but significant, resources used in combination to cure cancer in accordance with clinical guidelines. They are separate and distinct medical services with separate and distinct CPT code descriptors and separate payment under both the MPFS and HOPPS. The Agency must ensure that RO

Model payments are correct and accurately account for the cost of guideline concordant care, which involves these two distinct modalities of treatment.

As it is currently constructed, the cervical cancer rates fail to account for the total cost of guideline concordant care regardless of whether care is delivered in one setting by one physician or care transitions taking place between physicians and sites of service. Based on the 2015-2017 data issued with the proposed RO Model, the average allowed charges for the guideline concordant treatment of cervical cancer were $4,932 for the PC and $20,315 for the TC. In the final rule those rates are set at $3,829 and $17,581, respectively a reduction of 29% off the PC charges and 16% off the TC charges. The duplicate services (payment) construct and reconciliation against the episode payment made to the RO Model participant have the potential to create situations in which the FFS payments associated with services delivered by a second physician or at a second site of service may offset the episode payment by a considerable amount, making it nearly impossible for the RO Model participant to receive appropriate reimbursement for the service. This also has the unintended consequence of making it less desirable to transfer patients to other physicians or sites of service due to the reimbursement consequences. CMS must address this either through separate payments for cervical services to recognize guideline concordant care or through modification of the payment methodology to account for the true cost of guideline concordant care.

CMS did not make any of these modifications in the final rule and has seemed to totally of dismiss our concerns about the impact on cervical cancer care and this vulnerable patient population This underscores our concern that CMS is unwilling to ensure that payment rates are adequately set. The cervical cancer rate determination is particularly disappointing, as it is very clear that the data used demonstrated that inappropriate care was more frequently delivered between 2015-2017, rather than guideline concordant care. By not considering the cost associated with guideline concordant care, the Agency is falling into the trap of relying solely on fee-for-service payment data to determine payment and missing an incredible opportunity to apply payment policy to drive value. **ASTRO insists that the Agency reconsider the National Base Rates based on these recommendations. Additionally, we insist on transparency around the development of National Base Rates to ensure that they are accurately set and recognize guideline concordant treatment.**

<u>APM Incentive Payment</u>

At the same time, CMS is blatantly disregarding the statutory requirement that the Secretary focus on models expected to reduce program costs while preserving or enhancing the quality of care as is evidenced by the Agency's refusal to accurately price episodes based on guideline concordant care as previously described. While CMMI is using the statute as a basis to support significant cuts to radiation oncology participants, the Agency is waiving MACRA's statutory requirement to apply to the 5% APM Incentive Payment to covered professional services under the Medicare physician fee schedule, which clearly includes freestanding center technical payments. This waiver is a clear violation of the letter and spirit of MACRA, undermines community-based radiation oncology care and is likely to lead to consolidation. **CMS should comply with MACRA's legal requirements to provide RO Model QPs with the full 5% APM incentive payment bonus for both professional and technical payments.**

Furthermore, we are extremely concerned that the tiny shred of "upside" remaining in the model, the 5% APM incentive payment for professional services, will be compromised by, of all things, the delay in implementation. To qualify as a QP, a provider must meet certain thresholds that are set to increase through 2023.[2] In 2021, the provider must receive at least 50 percent of their Medicare Part B payments or see at least 35 percent of Medicare patients through an Advanced APM entity.[3] ASTRO is concerned that given the July 1, 2021 start date, only the December 2021 Snap Shot 3 period will apply to the RO Model, which would encompass data from July and August in that first performance period. This limitation would eliminate the ability of RO Model participants from achieving QP status, which would prevent them from securing the 5% bonus for participation. This amounts to another cut, on top of the aforementioned cuts.

ASTRO requests that CMS determine a methodology for ensuring that RO Model participants achieve Advanced APM status whether it is through designation of the RO Model as a capitated payment arrangement or through modification to the QP snapshot period.

Case Mix Adjustment

The Case Mix Adjustment is designed to account for age, sex, presence of major procedure, death at 30/60/90 days, and presence of chemotherapy. In response to the proposed rule, ASTRO urged CMS to modify the Case Mix methodology to account for differences in Case Mix between freestanding and hospital-based practices, which vary significantly. The Agency disregarded this recommendation. ASTRO followed up in a July 2020 letter to urge CMS to consider the impact of COVID-19 on Case Mix. Due to the pandemic, many patients are delaying care and presenting with more advanced disease requiring more costly care, which will not be adequately accounted for in the Case Mix methodology until the fourth year of the demonstration period. Again, the Agency disregarded this recommendation.

ASTRO remains concerned that the Case Mix Adjustment does not adequately account for patient acuity, particularly in the COVID-19 environment. We are disappointed that CMS was unwilling to share the methodology used to establish Case Mix in the final rule. **CMS has been very adamant that hospitals and healthcare providers make transparent pricing for medical services, yet the Agency refuses to share its own methodology for determining payment rates. This must stop and be replaced by transparency. All information used to determine payment rates must be shared with the radiation oncology community and participants to ensure that rates are appropriately determined. CMS should revisit the Case Mix Adjustment in an open and transparent way to ensure its accuracy and to address the impact of COVID-19.**

Historical Adjustment and Blend

In the proposed rule, ASTRO demonstrated how the blend, previously known as the efficiency factor, hurt "efficient" practices with lower historical costs. We are now seeing that play out in the final rule, as efficient practices have been able to input their Case Mix and Historical Adjustments into the payment methodology, demonstrating a significant reduction in payment compared to historical rates.

[2] 42 C.F.R. § 414.1430. *See also* CMS, Advanced Alternative Payment Models (APMS), https://qpp.cms.gov/apms/advanced-apms?py=2019.
[3] 42 C.F.R. § 414.1430. *See also* CMS, Advanced Alternative Payment Models (APMS), https://qpp.cms.gov/apms/advanced-apms?py=2019.

Additionally, practices deemed inefficient are set to experience even greater reductions in reimbursement. For many practices, this is because the methodology does an inadequate job of recognizing the appropriate use of more expensive technology, such as proton therapy. The blend is based on a practices Historical Experience Adjustment, which along with the Case Mix, is a black box methodology that cannot be replicated to ensure accuracy. **Again, ASTRO recommends that the Agency provide more transparency regarding the development of the historical experience adjustment to ensure its accuracy. The Agency must also modify the Blend so that it rewards efficient practices and provides a glide-path for inefficient practices, as it is intended.**

New Equipment and Service Lines

ASTRO was disappointed that the Agency did not give consideration to the establishment of a rate review mechanism to ensure that practices participating in the model would not experience financial disincentives for updating existing equipment, acquiring new equipment or installing new service lines that benefit patients. A rate review mechanism would reset the payment rates to recognize the costs associated with upgrades, new equipment and new service lines, so that practices could continue to provide patients with the highest quality care, without being penalized under a payment methodology based on historical payment rates that do not recognize the cost of these new items. Failure to account for new service lines creates an unfair and uneven playing field in certain markets. **ASTRO contends that the Agency consider the application of a rate review mechanism or some other formula for recognizing the need for upgrades, new equipment and new service lines. This is critical for radiation oncology, which relies heavily on these capital investments to ensure the continued delivery of high-quality care. Without such a mechanism, practices that are compelled to participate in the model will be unable to meet the evolving clinical needs of their patients and will be put at a clear competitive disadvantage in comparison to practices outside the model.**

Quality and Data Element Requirements

Data collection

ASTRO appreciates that CMS has been carefully considering and rolling back unnecessary regulatory reporting burdens through its Patients Over Paperwork initiative. However, this initiative conflicts with the significant new burden associated with quality and clinical data collection requirements in the RO Model, particularly given that practices will be spending a significant amount of time and resources shifting their business models to the new alternative payment model. Practices will have to create separate billing systems, hire additional staff and devote significant staff time to learning the model and completing model functions, all while still reeling from staff layoffs and hiring freezes associated with the ongoing pandemic. The more time spent on needless input of data that does not result in improved patient care is time poorly spent and a harmful distraction. **The Agency should consider a stepped approach to the implementation of data collection and reporting under the RO Model.**

Clinical Data Elements

As stated in ASTRO's response to the RFI for Clinical Data Element (CDE) reporting, we recommend both a delay and a phased approach for this requirement. Specialty societies are working with initiatives such as mCODE and CodeX to develop data sets that will provide meaningful oncology-specific data; however, this effort is still in the early stages. CDE collection, starting in 2022, should begin only with data elements that are codified within the HL7 international standards. By starting with a small data set, it

allows time for standards to be formalized, vendors to complete the necessary upgrades and physicians to change workflows to capture the required data. **The only CDEs collected for the five cancers should be: beneficiary ID, performance status, stage, treatment intent and prior radiation. ASTRO also requests that the Agency provide clarification on the collection mechanism and structure of these data elements well in advance of implementation.**

Monitoring Requirements
Similar to CDE collection, EHR vendors need time to develop discrete fields for the requested monitoring data elements as they may be typically captured in clinical notes or external systems. ASTRO remains concerned with the related financial costs that participants may incur, as vendor costs are shifted to radiation oncology clinics—adding more financial burden from the model. **ASTRO requests that CMS provide clarification on how this data is evidenced and what types of feedback, based on this data, will be provided to participants. RO Model participants require additional information to understand how to provide evidence of compliance with these requirements, particularly if the medical record does not currently collect this data, or if it is found in other systems or clinical notes.**

Patient cohort
CMS finalized its decision to require that data be reported for all applicable patients (not just Medicare fee-for-service (FFS) beneficiaries) for the 16 disease sites covered by the Model based on the numerator and denominator specifications for each measure. ASTRO continues to believe that reporting for all patients, regardless of Model inclusion, is an unnecessary burden, as it does not align with other reporting programs. **ASTRO requests that that CMMI limit quality measure reporting to Medicare FFS beneficiaries treated for one of the 16 disease sites covered by the Model.**

Plan of Care for Pain
ASTRO remains concerned about the measure specifications included for the Oncology: Medical and Radiation – Plan of care for Pain (NQF41 #0383; CMS Quality ID #144). First, the final rule states that participants must use the "most recent" measure, which indicates reporting for moderate or severe pain (2019 specifications); however, the provided measure specifications are for the 2018 measure. **ASTRO insists that the Agency follow through with its commitment to align RO Model quality reporting requirements with MIPS requirements. The Agency should confirm its intention that the 2018 specifications will be used in 2021, which includes all pain, not just limited to moderate or severe pain.**

Secondly, #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. Without the quantification measure, RO Model participants will not be able to ensure a correct denominator population to CMS. **ASTRO requests further information on how RO Model participants are to communicate this to CMS.**

Reporting
Through early conversations with CMMI, comment letters and other communications efforts, ASTRO has expressed major reservations about data reporting. We have consistently asked for the Agency to utilize the reporting mechanisms present in MIPS, which supports tools that many practices already have in use. However, to date, there is still no information on how data is to be reported under the model. This is especially concerning considering practices must have workflows in place prior to the start of a

performance year to collect the relevant data in an accurate and timely manner. **CMS must provide additional information on the reporting mechanism at least six-months in advance of the RO Model start date to allow adequate time for practices to modify workflow prior to the July 1 launch date. Additionally, we urge the Agency to utilize the same data collection and reporting tools that are available to clinicians participating in MIPS.**

MIPS

Program alignment
ASTRO continues to be concerned about the lack of alignment with the RO Model among other Medicare reporting programs. The Agency has a long history of committing to alignment of reporting systems, to ease the reporting burden of clinicians; so, we are alarmed to see that value not applied to the RO Model. MIPS, which many RO Model participants will be familiar with, has a low-volume threshold based on beneficiary count, charges and covered services. MIPS provides accommodations and exemptions for small and rural practices in multiple areas of performance. MIPS provides a variety of reporting options that are well established, some even from the days of the Patient Quality Reporting System (PQRS). The RO Model, to date, has none of these. Under the Medicare and CHIP Reauthorization Act (MACRA), the two arms of the Quality Payment Program (QPP) should be aligned, with MIPS providing the on-ramp for an Advanced APM. **ASTRO requests that the Agency use the RO Model implementation delay as an opportunity to realign the RO Model with MIPS and other reporting programs, thereby reducing burden and building upon a foundation of knowledge that many RO Model participants already have in place.**

Mid-year program transfer
Since the announcement of the RO Model delay, ASTRO has had concerns about the implications for MIPS eligible radiation oncologists. The delay of the Model highlights several questions that have not been completely answered by the Agency. First, how are the Model participants intended to participate in Medicare quality reporting for the first six months of 2021? What accommodations will be made for those practices that must report through MIPS because they are unsure if they will qualify as an Advanced APM through the RO Model? **ASTRO insists that CMMI provide clarification regarding these very realistic scenarios and make decisions in favor of the clinicians that are compelled to participate in the RO Model. These decisions should be communicated at least six-months prior to the RO Model implementation date.**

Advanced APM and MIPS APM Status

CMS intends for the RO Model to qualify as an Advanced APM and to also meet the criteria to be a MIPS APM. ASTRO insists that the Agency give full consideration to the RO Model's applicability as a capitated payment arrangement.

To be an Advanced APM, an alternative payment model must satisfy three specific criteria 1) Use of Certified Electronic Health Records Technology; 2) Payment Based on MIPS comparable quality measures; and 3) Meet the nominal financial risk standard. Another way of meeting the financial risk standard is through capitated arrangement:

> 42 C.F.R. § 414.1415(c)(6) - "a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all

items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses included or savings earned by the APM entity."

ASTRO understands the RO Model is a capitated payment arrangement in that it meets the definition set forth in 42 C.F.R. § 414.1415(c)(6) and insists that the Agency apply Advanced APM status to all RO Model participants. Otherwise practices will be caught up in meeting the qualifications required to achieve Advanced APM Qualifying APM Participant (QP) status.

Extreme and Uncontrollable Circumstances

The MIPS program includes an "Extreme and Uncontrollable Circumstances" exception, which allows practices that have experienced events entirely outside of their control to apply for an exception from the MIPS program during the year in which the event took place. A similar exception must be implemented in the RO Model to protect those practices that have been impacted by extreme and uncontrollable circumstances, such as a natural disaster, including hurricanes, fire, or public health emergency. **ASTRO has heard from practices compelled to participate in the RO Model that have not only been greatly impacted by COVID-19, but also by gulf coast hurricanes and California forest fires. These practices are just getting back on their feet and can barely muster the resources to reopen their doors, let alone implement or participate fully in the RO Model. The Agency must include an extreme and uncontrollable circumstances policy that allows practices the time they need to recover without the added worry involved in participating in the RO Model.**

We thank you for taking the time to review our concerns. ASTRO will continue to operate in good faith and look forward to opportunities to collaborate with CMS on implementing modifications to the RO Model, so that it may be a successful value-based effort. We appreciate the Agency's shared commitment to value-based care. We request an opportunity to review these recommendations with you, as well as other CMS decisionmakers involved in the RO Model. Please contact Anne Hubbard, ASTRO Director of Health Policy at 703-839-7394 or Anne.Hubbard@astro.org.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

cc:
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