The US Oncology Network

September 16, 2019

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
P.O. Box 8013
Baltimore, MD 21244-8013

**Re: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures (CMS-5527-P)**

Dear Administrator Verma:

On behalf of The US Oncology Network (The Network), which represents over 10,000 oncology physicians, nurses, clinicians, and cancer specialists nationwide, including 236 radiation oncologists, thank you for the opportunity to comment on the *Specialty Care Models To Improve Quality of Care and Reduce Expenditures (CMS-5527-P)*, in particular the proposed Radiation Oncology (RO) Model.

The Network is committed to working with the Centers for Medicare & Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation (CMMI) to enhance the delivery of cancer care and protect patient access to high-quality care in the most efficient manner. We are one of the nation's largest and most innovative networks of community-based oncology physicians, treating nearly 1 million cancer patients annually in more than 450 locations across 25 states. The Network unites more than 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, most cost-effective integrated cancer care to help patients fight cancer, and win.

As demonstrated by the 15 Network practices participating in the Oncology Care Model (OCM), The Network is a leader in practice transformation and a partner in the transition to value-based care. We believe our breadth of experience providing cancer care and our active participation in the OCM greatly informs our ability to provide feedback on the proposed RO model. We look forward to working with CMS to ensure this program provides care of the greatest quality for the patients we serve.

For years, The Network has advocated for an alternative payment model (APM) to promote quality outcomes and provide payment stability in RO, and we applaud CMS for taking the necessary first step in crafting this model. As community-based providers who have long raised awareness of the negative consequences of payment disparity across sites of service, we are particularly encouraged by CMS' commitment to site neutrality in the proposed RO model. However, our analysis of the RO model, as currently proposed, has identified significant flaws in the Base Rate calculation, and we believe it would add material financial and administrative burden on participating practices. As further detailed in our comments below, The Network urges CMS to adopt the following recommendations in order to maintain the viability of freestanding radiation therapy centers:

- Improve accuracy of the National Base Rates by employing a blend between Physician Fee Schedule (PFS) and Outpatient Prospective Payment System (OPPS) data for the Professional Component (PC) and applying clinical business rules as laid out below and further explicated by the American Society for Radiation Therapy (ASTRO);
- Adhere to CMS' goal of 3% savings as discussed in the regulatory impact analysis in the proposed rule; and
- Maintain the 5% Technical Component (TC) incentive payment required under MACRA.

To facilitate your review, we have broken our comments into the following sections:

***Mandatory Requirement***

The Network has long raised concerns over mandatory demonstration models in Medicare and believes the proposed RO model should be voluntary. The success of properly constructed, voluntary APMs with sizeable patient and provider enrollment—notably, the OCM—illustrates that there are ways to encourage practices to voluntarily accept the challenge of managing all aspects of a cancer patient's care and see meaningful results.

If CMMI decides the RO model will remain mandatory, we believe further action is necessary to reduce the risk and disruption presented by the model as currently proposed. Specifically, we would encourage CMS to:

- Decrease the total number of providers required to participate and phase in the model over time. Rather than the proposed 40% mandatory participation in the first year, we recommend CMS phase in the number of participants throughout the course of the model. This could be done on a voluntary basis for the first year, to allow the most sophisticated practices to test the model before expanding it to 10% the second year, 20% the third year, and 30% by the fourth year; and
- Provide a hardship exemption for smaller practices that may not have the administrative and financial resources to assume the kind of work and risk associated with the model. Failure to do so may lead to further conversion of freestanding physician practices into larger health systems—a trend CMS has been concerned about in the OPPS context.

We believe it is critical to provide flexibilities to providers if they are mandated to participate to ensure providers are not in any way disproportionately burdened based on a random selection.

***Start Date***

The proposed rule seeks comment from stakeholders regarding the start date of the RO model and offers January 1, 2020 or April 1, 2020 as potential dates. We believe both of these dates are premature, given the heavy burden associated with preparing to participate in the RO model for providers in yet-to-be-announced core-based statistical areas (CBSAs). In addition, significant burdens will be imposed on electronic health record (EHR) vendors, which will require months of preparation as they develop new computer code, test changes and ultimately deliver software updates to providers, who will in turn need to be trained on the program before testing it within their systems.

The Network has considerable experience in setting up new models from our extensive work in the commercial market and participation in the OCM. Based on that experience and the necessity of new IT

system support, support staff training, and retooling of workflows, we urge CMS to set a start date of January 1, 2021. If CMS proceeds with a 2020 start, then we suggest that it take the approach proposed in its recent Voluntary Kidney Models—that is, using the first year as a "year zero" to work with participants to stand up the model, with the second year being the first performance year.

At a minimum, we believe implementation should begin no sooner than 9 months after CMS announces the selected CBSAs. At present, unlike prior mandatory demonstrations, CMMI has given no indication of which CBSAs would be included in the RO model thereby creating uncertainty for the provider community. Under the proposed Comprehensive Care for Joint Replacement Model, originally a mandatory participation model, the list of impacted areas was announced when the model was proposed which was more than 8 months prior to the proposed start date. Even the subsequently cancelled Advancing Care Coordination models allowed for 5 months between the publishing of mandated participation locations and the start date. Practices must have adequate time to prepare their operational infrastructures in order for the model to be successful.

***Providers Operating Across Included and Excluded CBSAs***

In the proposed rule, CMS proposes that the RO model unit of organization would be based on the CBSA. However, the level of organization of practices in The Network is based on tax identification numbers (TINs), and a number of practices operate in multiple locations across two or more CBSAs (within the same TIN). Under the proposed rule, one practice location could be included in the model while others are not. This may prove difficult for both providers and patients and could cause avoidable complexity in rare situations where patients shift between facilities. We recommend that if practices have a portion of their providers included in the mandatory CBSA, they should be able to request that their entire practice opt-in or opt-out of the RO model. This would spare them from operating under two different Medicare payment structures.

***Beneficiary Population***

CMS asks for comments in the proposed rule on whether patients should be able to opt out of the RO model. While we believe that care coordination in a future RO model will be positive for patients, they should always have a choice in their care. Therefore, we believe that a patient opt-out provision is warranted just as it is in the OCM.

***Payment Methodology and Financial Impact***

CMS estimates the RO model will save Medicare $250 million over 5 years (p. 310) and indicates that the model's expected savings will come only from the discount factor. However, there is a wide range in the potential impact, between $50 million and $460 million. Moreover, CMS notes (p. 317) that it lacked complete information regarding the data sources and underlying methodology for withhold reconciliation when it conducted its impact analysis.

The proposed RO model additionally discusses an estimated savings impact of 3% of Medicare spending in the regulatory impact analysis. However, the model proposes a 4% discount rate for the PC and a 5% discount rate for the TC. These discounts are in addition to 3 distinct withholds that eligible providers may not be able to fully recoup. Our initial analysis, summarized below, shows the RO model will result in significant reductions in reimbursement to practices well beyond the 3% range when accounting for the undervalued Base Rates, discounts, withholds, and adjustments. For reference, in the OCM, our practices performed in the quality measures in the 70th percentile, on average. If the radiation centers

performed similarly, this could result in an additional withhold of roughly 0.5% for quality, 0.5% for patient satisfaction, and perhaps 0.5% for reconciliation of incomplete episodes, for a total of around -1.5%. Added to the built-in discount of 4.8% for dual participants, the total decrease from the expected payment would be more than double the 3% savings target. **To ensure stability and predictability, we ask CMS to clarify the precise savings estimate and establish guardrails to ensure that the reductions to providers do not excessively expand beyond that target.** Given the impact on these withholds to practice cash flows, The Network also recommends that CMS apply a forward fund of the withholds, which will therefore limit the funds that do not get released until the 20-month reconciliation and true-up process after the performance year.

We further urge CMS to conduct and make available for further notice and comment, a full scale, comprehensive analysis of the expected savings that considers factors beyond just the discount adjustment and reparametrize the adjustments to ensure total reductions are not expected to exceed $250 million. In weighing the impact of the proposed model's discount and withholds, we urge CMS to consider the impact on freestanding RO providers. Due to the high fixed-cost nature of radiation therapy—a subject we have previously discussed with CMS—negative impacts on reimbursement have potentially large adverse effects. We worry the RO model could lead to further consolidation into larger health systems, a trend CMS has expressed concern about in the past.

Of additional concern, we strongly believe that CMS has severely underestimated the costs and administrative burden of adjusting to and complying with this model. Based on our experience with the OCM and our understanding of the resources needed to comply with the RO model, we estimate that the costs of adjusting to this model could be well over $400,000 in Year 1 and nearly $350,000 per year following Year 1 for a medium-sized practice. In the OCM, these operational costs have exceeded $3 million per year across The Network. These conservative estimates assume software, EHR and IT updates along with outside services and roughly 0.3 FTEs per physician to account for the newly created workflow related to revenue cycle processes as well as quality metric and other data documentation, collection, and reporting that will exist alongside the current workflow already established for patients outside of the RO model. The relative impact of these costs could be much greater for small or rural practices that will have to incur the same programmatic costs as larger practices, but with much less ability to absorb them. It will be particularly burdensome for practices in multiple CBSAs with regional billing offices and providers who float between locations to properly identify participating patients and bill accordingly. **We encourage CMS to further account for the costs associated with model implementation and the disproportionate impact on small rural providers, including incorporating a funding mechanism to cover and stabilize long-term practice transformation, as seen in other APMs.**

***National Base Rate***

Overall, we have a number of concerns with the National Base Rates, as proposed. An internal analysis described below finds these rates to significantly undervalue RO services. We share the concern expressed by ASTRO with respect to exclusion of complete RO data—particularly the PC—in the calculation of the National Base Rate. CMS' comment that OPPS payment has been more stable than the PFS data is particularly puzzling since major RO PFS codes have been frozen since 2015. A more rational approach would be to use a blend between PFS and OPPS for the PC. This would still preserve CMS' preference for OPPS data for the TC.

**In addition, we support ASTRO's proposal to establish clinical business rules and urge CMS to remove both partial/ incomplete episodes and episodes of palliative care.** We believe that the National Base Rate calculation for the 15 diagnostic groups that account for the definitive management of localized cancers (all diagnostic groups other than Brain or Bone Metastases) include episodes of metastatic cancer treated with less fractions of radiation and lower intensity (2D and 3D conformal therapy versus IMRT) that were misattributed as primary management. Further, the episodes for high-risk prostate cancer and gynecological malignancy do not include subsequent management with brachytherapy, thus lowering their base rate payment.

The Network, in an attempt to replicate the National Base Rates in the proposed rule, performed an internal analysis of 5,727,813 radiation therapy claims within The Network from January 2017 through July 2019. These claims represent 71,978 unique episodes of care as defined by the proposed RO model. After applying several clinical rules to remove palliative episodes in definitive disease sites and reattributing the removed episodes to the appropriate metastatic disease site, we determined the Base Rates for each of the disease sites are too low. According to The Network's claims analysis, the Base Rates should be 5.75% higher based on a simple average of the difference across each disease site and 3.7% higher based on a weighted average of the frequency of each disease site. These differences range from 0.15% for lymphoma to 35.23% for kidney cancer. See Table 1 for results for each disease site.

**Table 1. CMS Base Rates vs. The Network's Estimates**

| Disease Site | Difference between CMS Base Rate and New Base Rate after Clinical Rules |
|---|---|
| Anal | 1.48% |
| Bladder | 9.94% |
| Bone Metastases | 3.65% |
| Brain Metastases | 4.96% |
| Breast | 1.69% |
| CNS Tumors | 2.41% |
| Cervical | 3.27% |
| Colorectal | 5.51% |
| Head and Neck | 1.31% |
| Kidney | 35.23% |
| Liver | 4.06% |
| Lung | 9.72% |
| Lymphoma | 0.15% |
| Pancreatic | 3.20% |
| Prostate | 3.98% |
| Upper GI | 5.93% |
| Uterine | 1.27% |
| **Average** | **5.75% (3.7%, volume weighted)** |

From this analysis, we identified 3 major issues with the claims-based approach underlying the proposed Base Rates:

1. Incorrect ICD10 coding that misattributes episodes to incorrect disease sites;
2. Claims data that only includes partial episodes—for example, we observed the brachytherapy portion of an episode where the EBRT was completed at a different site or missing brachytherapy codes due to a change in site of service; and
3. Practice-specific variations in code modifiers that may inadvertently exclude codes and episodes.

This analysis is in alignment with ASTRO's analysis that used a blend of PFS and OPPS for the PC and OPPS for the TC and applied similar clinical rules to remove palliative episodes. ASTRO's analysis similarly found that the global (combined PC and TC) National Base Rates should be approximately 3% higher on average (6.7% higher when accounting for the volume for each disease site). Key differences in the ASTRO analysis and the analysis presented here include the use of PFS data only for our analysis of freestanding centers and an inherently different distribution of episodes in The Network compared to CMS' RO Episode File. Table 2 highlights the major differences in the distribution of episodes in The Network compared to CMS' RO Episode File.

**Table 2. Distribution of Cancer Cases - National Data vs. The Network**

| Disease Site | Frequency | | | | |
|---|---|---|---|---|---|
| | CMS Cases | | | The Network's Claims Data | |
| | All Cases | OPD Cases | FREE Cases | Average | Range (Min-Max) |
| Anal | 0.95% | 0.95% | 0.97% | 1.30% | 0.25 - 2.03% |
| Bladder | 1.47% | 1.41% | 1.57% | 0.85% | 0.43 - 2.59% |
| Bone Metastases | 9.44% | 8.49% | 11.15% | 12.44% | 5.91 - 16.95% |
| Brain Metastases | 6.19% | 6.73% | 5.23% | 6.51% | 0.91 - 10.6% |
| Breast | 21.87% | 22.38% | 20.92% | 31.02% | 15.53 - 55.76% |
| CNS Tumor | 1.95% | 2.20% | 1.48% | 1.92% | 0 - 3.17% |
| Cervical | 0.57% | 0.63% | 0.46% | 1.68% | 0 - 4.21% |
| Colorectal | 3.11% | 3.28% | 2.80% | 3.91% | 1.57 - 6.08% |
| Head and Neck | 5.72% | 5.86% | 5.47% | 5.80% | 1.12 - 14.63% |
| Kidney | 0.45% | 0.55% | 0.26% | 0.20% | 0 - 0.65% |
| Liver | 1.02% | 1.29% | 0.52% | 0.50% | 0.1 - 1.02% |
| Lung | 19.21% | 20.86% | 16.22% | 11.36% | 3.51 - 21.44% |
| Lymphoma | 3.36% | 3.50% | 3.12% | 3.15% | 1.98 - 5.94% |
| Pancreatic | 1.35% | 1.50% | 1.06% | 1.14% | 0.37 - 2.24% |
| Prostate | 17.67% | 14.26% | 23.88% | 11.77% | 3.6 - 32.96% |
| Upper GI | 2.85% | 2.92% | 2.72% | 2.65% | 0.74 - 4.16% |
| Uterine | 2.83% | 3.21% | 2.15% | 3.81% | 0.1 - 11.07% |

The Network has a unique distribution of episodes in many disease sites compared to the OPD, FREE, and all episodes in the CMS RO Episode File. Given that CMS is using the OPD data to calculate the national base rates (including PC and TC), large differences in episode distributions are observed.

The Network's analysis confirms ASTRO's analysis and suggests that the National Base Rates are at least 3 - 7% lower than what would be expected, with possible larger variations by clinical disease site and by RO participant.

**The Network encourages CMS to consider applying similar clinical rules and also blending the PFS and OPPS for the PC portion of the payment.** Given the differences in case mix between freestanding and OPD, as well as a varying distribution of types of episodes per disease site between practices, The Network requests further clarification on the impact of the case mix adjustment coefficients on a community practice's predicted versus expected payments and the impact on the combined adjustment that a practice can expect in the RO model.

We recommend CMS re-estimate the Base Rate for these 15 diagnostic groups and remove all episodes of 1-10 fractions with 2D or 3D management. This will remove non-SBRT patients. Further, we would suggest that either brachytherapy as a modality be removed from the model, or additional diagnostic groups be created to capture the increased costs of combined external beam and brachytherapy for prostate and gynecologic malignancies.

We applaud CMS for considering the unique circumstances that may have contributed to different historical trends but also agree with MedPAC and ASTRO that the model runs the risk of penalizing efficient practices. For example, practices that were historically "efficient" during 2015-2017 may have adopted greater utilization of hypofractionation. These practices are penalized in the RO model by a downward adjustment from the National Base Rate. To address this, the impact of the historical adjustment should be adjusted downward and the impact of the efficiency factor should be increased progressively over the five years of the model.

Lastly, the National Base Rates for prostate cancer and for gynecologic malignancies do not reflect the increased costs of combined modality care, a view we share with the American Brachytherapy Society. The rates are driven by the large volumes of patients who receive external beam radiation alone. However, multiple peer-reviewed studies over the past two decades have shown improved tumor control outcomes with combined modality EBRT/brachytherapy for Stages II and III cervix cancer. A SEER database analysis of 7,359 patients between 1998 and 2009 reported a 25% reduction in brachytherapy use which resulted in a 13% reduction in cause-specific survival for women with cervical cancer[1]. A large meta-analysis recently confirmed that for poor-prognosis intermediate-risk and high-risk prostate cancer, implant and EBRT were equivalent to prostatectomy, and superior to EBRT alone (3D-EBRT or IMRT)[2]. The Network is concerned that the RO model will not sufficiently compensate providers for these patients, and, worse, may result in less than optimal care if access to brachytherapy is compromised as a result.

We would offer two ways to ameliorate this potential problem:

1. For patients who receive external beam radiation, reimburse brachytherapy services as FFS; or

[1] Smith GL, Eifel PJ: Trends in the utilization of brachytherapy in cervical cancer in the United States: In regard to Han et al. Int J Radiat Oncol Biol Phys. 2014;88:459-460.

[2] Kishan AU, Cook RR, Ciezki JP, et al. Radical Prostatectomy, External Beam Radiotherapy, or External Beam Radiotherapy with Brachytherapy Boost and Disease Progression and Mortality in Patients with Gleason Score 9-10 Prostate Cancer, JAMA March 6, 2018 Volume 319, Number 9 89.

2. CMMI could create two additional diagnostic groups: a) prostate cancer treated by combined modality external beam and implant and b) gynecologic malignancy treated by combined modality external beam and implant or to allow the triggering of two separate bundled payments for combined-radiation modality episodes.

Based on analysis of 1,151 episodes of cervical cancer in The Network within a 2.5-year period, the proposed Base Rates do not adequately cover the cost of combined radiation modality care, such as IMRT followed by brachytherapy. Additionally, misattribution of episodes to the bundle and only partially treated episodes significantly decrease the calculated Base Rate. For instance, 2D/Complex EBRT episodes rarely occur in a definitive setting for cervical cancer but are attributed to cervical cancer episodes based on the RO model methodology. Additionally, HDR brachytherapy as a monotherapy is also rarely used for cervical cancer but is seen in 9% of episodes in The Network's claims data, which likely reflects partially captured claims data.

There is precedent in the OCM for recognizing either increased or decreased cost for delivering the appropriate care. In the OCM, breast, prostate, and bladder cancer predicted costs were problematic. Breast cancer costs were then recomputed during the OCM depending on whether the patient received hormone therapy only or other systemic therapies. Modifications of predicted costs of prostate and bladder cancer were similarly constructed. These additional diagnostic groups would be a similar bifurcation of one disease state into two.

***Operational Complexities***

Beyond the clinical protocols that will need to be addressed, there are significant billing and operational matters that will affect beneficiaries and practices. A critical example is beneficiary coinsurance. CMS assumes that practices will develop beneficiary-friendly payment schedules to accommodate for the two-episode payments in the model. However, CMS seems not to have recognized that many fee-for-service (FFS) beneficiaries have Medicare Supplemental Insurance ("Medigap") which operates under FFS claims payment rules. With that in mind, we ask for clarification on the following questions:

1. How will the bundled payments work with the crosswalk to the Medigap (secondary) payers? Historically, once Medicare Part B pays, if the member also has a Medigap payer on file, Medicare will automatically crosswalk to the Medigap payer to process and pay the 20% coinsurance based on plan benefit design.
2. Will the Medigap payers be able to process and pay bundled payment amounts and accept the new coding (modifiers) within the RO model?
3. How do the withhold amounts work with Medigap payers?
4. Will the member's 20% coinsurance be applicable with/for the withhold amounts?
5. With the reconciliation needed with/for the withhold amounts in the RO model, is the member's 20% coinsurance applicable to the withholds?
6. Assuming the member's 20% coinsurance is applicable to the withholds, how will CMS ensure that reconciliation is completed within the timely filing rules of the Medigap payer, to prevent the member's Medigap-covered benefits from being impacted and the provider from being financially disadvantaged?
7. Could CMS consider basing its patient cost-sharing on the lesser of the patient portion in cost-sharing under standard Medicare payment amounts for the specific services the patient

received versus the 20% of the bundled payment amount? This approach may allow patients to benefit from efficiencies within the bundled model.

***New Technology and New Lines of Service***

By its nature, RO is rooted in the use of high-technology, which continues to evolve, enabling more precise and effective applications that can improve patient outcomes. While incremental changes may need modest adjustments in the RO model's trending factor, the more important question is how CMS should recognize new technology. We recommend that existing policies and procedures for new technology under the OPPS for new device pass-through payment can serve as the framework. In this way, all stakeholders understand the rules of the road, and beneficiaries being cared for under the RO model are not disadvantaged relative to all other Medicare beneficiaries. We also recommend CMS create a pathway for practices to add new service lines without penalty within the RO model. The new service lines could be paid under FFS for a period of time until the costs of the new service line are adequately incorporated into the rolling historical practice costs.

***Medicare Program Waivers***

CMS is proposing to waive the 2015 Medicare Access and CHIP Reauthorization Act (MACRA) statute that includes a 5% TC incentive payment, meaning the 5% Advanced APM (AAPM) incentive payment will only apply to PC services, despite technical payments still being subject to the discount and withhold factors. The use of this waiver authority is unprecedented in any other CMMI model and defies the intent of MACRA to use the 5% bonus payments as incentives to assist physicians' and practices' move toward value-based payment. Further, we share ASTRO's view that there is no legal or policy basis for CMS' conclusion that the RO model's goal of site neutrality is served by eliminating a payment that radiation oncologists at freestanding clinics would otherwise be entitled to receive. **The Network strongly urges CMS to not apply the 5% discount factor to TC – or alternatively – to ensure that the 5% APM bonus payment applies to both the TC and PC.** Clinicians who are forced to participate in a mandatory model and absorb significant operational costs, should not also see their AAPM bonuses cut.

***Proton Beam Therapy***

Proton beam therapy is a revolutionary, highly-specialized, and promising treatment option for cancer patients with tumors in sensitive areas where conventional radiation therapy may result in increased and avoidable risk. Using sub-millimeter precision that delivers high-energy proton beams directly to tumors, proton therapy can often minimize damage to surrounding healthy tissue.

CMS proposes to include proton beam therapy in the RO model, except when the beneficiary is part of a federally-funded, multi-institution, randomized controlled trial. While we understand why CMS believes that proton beam therapy should be part of the model, the practical effect of this proposal on non-facility proton centers is significant and runs the risk of disadvantaging non-facility providers and potentially shifting patients to the exempt, but more costly care settings.

***Quality Measures***

CMS proposes to require participants to report basic, clinical information such as cancer stage, disease involvement, treatment, and specific treatment plan information on RO beneficiaries treated for five types of cancer. CMS notes this information is not available in claims or captured in the proposed quality measures. We believe that the 5 diagnoses are correct, given the preponderance of these patients seen in most RO practices. We offer the following recommendations:

1. Staging
    a. For the three primary cancers we believe that general staging information (TNM) using the AJC staging system and the histology of the malignancy should suffice;
    b. In order to demonstrate the need for combined modality therapy (i.e., combination external beam and implant) for prostate cancer, either the "D'Amico" or the NCCN risk group should be reported;
    c. For bone metastases, the site of the lesion (e.g, weight-bearing bone, vertebrae, rib, other) should be reported and whether this is a solitary or multiple metastasis should be reported;
    d. For brain metastases, the number of metastases should be reported;
    e. For all patients, some measure of patient performance status (Karnofsky Performance Status or ECOG status) should be reported;
    f. For all patients whether radiation is the sole anti-neoplastic agent or whether chemotherapy, hormone therapy, or immunotherapy is also being administered concomitantly should be reported.
2. Treatment Intent
    a. We believe every patient within the 5 diagnoses category should have treatment intent reported as curative, palliative or benign;
3. Specific Treatment Plan Information
    a. We believe site of treatment, dose specification (e.g., "95% of specified dose to 95% of the planning treatment volume") and number of fractions should be reported. This is clinical information that should be readily available from the EHR and electronic radiation prescription. However, it may not be in exportable form at the outset of the model. Until this data is readily and easily exported, we recommend that the clinical data reporting should be optional.

***Data Collection***

The proposed rule lists a large number of requirements that will not be reported but will be monitored by EHR audits and site visits. These includes documented peer review, guideline adherence, and financial counseling, etc. There is no information about expected levels of compliance or penalties for non-compliance. If participants are going to be held to some standards or thresholds through monitoring and/or audits, then it is incumbent on CMS to provide that information in advance.

CMS also proposes to mandate collection of data about services to non-Medicare beneficiaries. Some of these services will have to be done manually for some period of time under the model and therefore incur additional labor costs for these non-Medicare patients. CMS says that the data for patients outside the model (under 65 years old) is acceptable since CMS is receiving the data in aggregated de-identified form, but practices still have to gather the data in patient-level form. We see little if any evidence that CMS has adequately estimated the impact of these costs on practices in its impact analysis. Until such information can be provided, we urge CMS to delay data collection to at least the second year of the model.

***Consumer Assessment of Healthcare Providers and Systems (CAHPS)***

We would also add a cautionary note on "patient experience" measures based on the CAHPS. The quality of the patient experience is a critical factor to assess in any clinical setting or episode but older patients who receive a survey 6-9 months post-treatment frequently forget specifics of their

interactions with providers. They may have also undergone multiple treatments, including chemotherapy, and may conflate their feelings about the disease with their experiences.

***Overlap with OCM***

The Network is proud to support over 900 physicians participating in the OCM. Due to the practice transformation focus and investments made by The Network's OCM practices, patient care has been enhanced. Moreover, our practices alone have realized more than $80 million in savings for Medicare through participation in the OCM.

As CMS notes in the proposed rule, there may be situations in which the RO model participants' care of patients overlaps with the OCM. We encourage CMS to take practices' investment in the OCM into consideration so the RO model is implemented with minimal disruption. We support CMS' proposal to make pro-rata payments and ask that it provide additional information on how this will be implemented so as not to disadvantage participants in either model. The OCM, for example, was phased-in overtime before two-sided risk was implemented. In contrast, the RO model, as proposed, would require significant two-sided risk with bundled payments taking the place of FFS on Day 1. CMS may want to consider a phase-in or blend of these payments to minimize disruption in the OCM.

***Conclusion***

On behalf of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide our comments on the proposed RO model. We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Sincerely,

Marcus Neubauer, M.D.
Chief Medical Officer
The US Oncology Network

Christopher M. Rose, M.D., FACR, FASTRO
Chief Radiation Oncologist
The US Oncology Network