September 16, 2019

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
P.O. Box 8013
Baltimore, MD 21244–1850

BY ELECTRONIC DELIVERY

Re: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures

Dear Administrator Verma:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the proposed Radiation Oncology (RO) Model described in the proposed rule published by the Centers for Medicare & Medicaid Services (CMS) (the Proposed Rule).[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 25,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC is deeply committed to promoting patient access to the most effective cancer treatments that are medically necessary given a patient's individualized needs. We further believe that it is vitally important to encourage ongoing innovation in the delivery of cancer care for all Americans. We are entering an exciting new era for cancer care with vast potential for breakthrough innovations that could reshape cancer treatment. New medical advances in radiation oncology continue to expand the treatment toolkit of health care professionals, and more technological developments are on the horizon in this rapidly evolving area of cancer care. New radiation therapy (RT) modalities carry transformative potential and may allow practitioners to reach significant numbers of patients for whom there might otherwise have been no effective treatment. We strongly believe that Medicare payment policies – including policies for value-based payment models under the agency's CMMI authority – should recognize and encourage the adoption of these advances and thereby promote access to these medical innovations as soon as they are approved by the Food and Drug Administration (FDA).

[1] 84 Fed. Reg. 34,478 (July 18, 2019).

ACCC especially appreciates the opportunity to comment on CMS's proposals related to this important model. ACCC and its members have long been at the forefront of the movement toward value-based payment, with many of our members voluntarily participating in CMS-sponsored models like the Oncology Care Model (OCM) and other value-based arrangements with partners across the health care system. Our members are committed to value-based care because we believe that this movement holds the promise of delivering higher quality care at a greater value for patients, providers, and the health care system. Our members' years of participating in, leading, and developing value-based payment systems gives ACCC an unusually deep perspective on what has worked and what has not worked in these systems, and we look forward to bringing this experience to the table in collaboration with CMS as you finalize the RO Model.

As an initial contribution to this discussion, we offer the following comments on the proposed RO Model. Our comments are the product of our members' collective experience and expertise as front-line providers of cancer care and as leaders in the drive toward higher-quality, more cost-efficient health care. In the comments below, ACCC urges CMS:

(1) To make significant changes to the proposed episode payment methodology to ensure that the RO Model will incentivize innovative and cost-efficient care and allow for equitable treatment of model participants, including specific comments with respect to (a) the disproportionate effect of payment cuts under the proposed model; (b) the trend factor; (c) the case mix adjustment; (d) the efficiency factor; (e) an adjustment to allow for the adoption of new technologies; (f) an adjustment for the stage of cancer in a given episode; (g) a process to allow for the establishment of new service lines; and (h) advance notice of payment rates under the model;

(2) To phase in mandatory participation in the RO Model to promote an equitable opportunity for success and ensure accurate and useful results from the model;

(3) To delay the beginning of the model until no sooner than July 1, 2020;

(4) To finalize its proposed exclusion of radiopharmaceuticals and certain brachytherapy surgical procedures from the services covered by the bundled payment;

(5) To begin a new RT episode when a new course of treatment begins before a pending 90-day RT episode is complete;

(6) To clarify certain aspects of the proposed quality reporting requirements;

(7) To reconsider the uncompensated burden that would be required to comply with the proposed monitoring and peer review requirements, which are not tied to pay for reporting;

(8) To apply the 5% Advanced Alternative Payment Model (APM) incentive payment to the technical component of RO Model payments as well as the professional component;

(9) To structure the final RO Model so that all RO Model participants will be qualifying participants in an Advanced APM for purposes of the Quality Payment Program (QPP), assuming minimum participation requirements are met;

(10) To open the RO Model to voluntary participation by Medicare Advantage plans and other payers; and

(11) To clarify how the RO Model will overlap with the OCM in a manner that allows for full and fair participation in both models.

I. ACCC urges CMS to make significant changes to the proposed episode payment methodology to ensure that the RO Model will incentivize innovative and cost-efficient care and allow for equitable treatment of model participants.

ACCC is a strong and longstanding supporter of CMS's effort to shift the health care system toward paying for care in a way that gives providers and others an incentive to generate innovative and more efficient approaches to care delivery, while ensuring that the quality of care remains high. Unfortunately, that is not what the RO Model's proposed episode payment methodology would do. Under the Proposed Rule, CMS would automatically reduce payment for all RT professional services by 4% and all RT technical services by 5%, would withhold and potentially retain additional amounts for quality and patient experience measures, and would institute a site-neutral policy that would have a disparate negative impact on many cancer centers. Taken together, these policies amount to a cut in Medicare expenditures that CMS itself estimates at $260 million over the course of the five-year model, which includes cuts to fee-for-service payments that CMS estimates at $200 million. At the same time, CMS estimates that RO Model participants would receive only $12 million in Advanced APM incentives under the QPP over the course of the model. The American Society for Radiation Oncology (ASTRO) has estimated an even deeper impact of minus $320 million over the term of the model, which amounts to a 5.9% cut in payment to providers.

Moreover, because CMS proposes to apply these significant payment cuts through up-front discounts and withholding, many providers that otherwise could achieve the type of efficiencies that CMS seeks to promote will be unable to do so because they will lack the cash flow required to make the necessary investments. The estimated payment cuts above do not even consider the likely cost of hiring new staff, purchasing new systems, and making other fundamental practice transformations that will be required for a model participant merely to break even. The OCM's monthly payments recognized the need for this infusion of funds to enable such investment in care improvements; the proposed RO Model includes no such infusion.

This is not an APM; it is simply an austere cut in reimbursement for the necessary treatment of patients battling cancer. Unlike every other model that CMS has adopted through the Center for Medicare and Medicaid Innovation (CMMI), whether voluntary or mandatory, the proposed RO Model would offer no opportunity for shared savings or other positive incentive. (The APM incentive is not part of the RO Model; rather, it was intended by Congress to be a financial reward for clinicians that elect to take the leap of participating in a model with two-sided risk in the first place. And, as noted below, some RO Model participants would not even receive the APM incentive under CMS's proposal.) This proposed structure risks forcing providers simply to cut necessary care or limit their RT offerings to those that they can continue to offer under the reduced reimbursement rates without going out of business.

ACCC and its members are deeply concerned that the ultimate effect of the proposed model would be a reduction in Medicare beneficiaries' access to necessary RT services, more uniformity in RT treatment as opposed to more innovation, and static or lower quality of care. This is the exact opposite of what Congress authorized CMMI models to do under Section 1115A of the Social Security Act (SSA), and indeed we question whether that statute authorizes a "model" that simply cuts reimbursement for a randomly selected group of Medicare providers and leaves them to figure out how to keep the doors open while continuing to provide necessary care. We urge CMS not to finalize the proposed model and instead to work with stakeholders to finalize a model that truly promotes and rewards innovative and cost-efficient delivery of RT services, as CMMI models are intended to do.

In addition, ACCC offers the following comments on specific aspects of the proposed episode payment methodology.

Disproportionate impact of reimbursement cuts

ACCC urges CMS to reconsider proposed policies that would disproportionately affect certain RT providers and suppliers. First, CMS's proposal to establish national base rates for episodes based solely on historical rates under the Hospital Outpatient Prospective Payment System (OPPS) would disproportionately harm freestanding RT clinics, which are reimbursed for both the professional and technical component of RT services under the Medicare Physician Fee Schedule (PFS). CMS states that its own analysis of Medicare payment for RT services indicates that freestanding RT clinics received approximately 11% more per RT episode than hospital outpatient departments. CMS further concludes that this difference in payment is due to differences in the payment methodology as between the PFS and OPPS, rather than any justifiable difference between the services furnished. ACCC requests that CMS share the details of its calculation that freestanding RT clinics received 11% higher reimbursement per episode than hospital outpatient departments, not just the data on which the calculation was based.

In addition, we were surprised by CMS's transparent acknowledgement that it is using the proposed RO Model to implement site-neutral payments in part because the agency does not have the statutory authority to adjust payment amounts outside of the established payment methodology for the PFS. This proposal effectively uses CMS's authority under Section 1115A to adopt a policy preference that CMS otherwise cannot adopt.

Moreover, we believe it is highly questionable that CMS will be able to "test" this site-neutrality policy at all. CMS is unlikely to be able to distinguish the effect of the site-neutrality policy from the more substantial effect of the across-the-board reimbursement cuts and payment rates established for types of cancers. Likewise, CMS's proposal to set a single payment rate for the technical component and the professional component for each type of cancer, regardless of modality, could confound a test of site-neutral payment.

We also are concerned that CMS's imposition of a mandatory model for RT services will disproportionately affect cancer centers with a predominantly Medicare patient base. We urge CMS to incorporate into the RO Model an easy-to-apply hardship exception, adjustment to the base rate, or other accommodation to ensure that RT providers and suppliers with a mostly Medicare patient base

are not overwhelmed by the proposed reimbursement cuts under the RO Model and have a fair opportunity to participate in the model along with participants who will be cushioned by a more diverse patient mix.

Trend factor

CMS proposes to apply a trend factor to the base rates, using PFS and OPPS rates outside the RO Model. We support the proposed trend factor, which smooths out differences between participants and is one of the only available protections that RO Model participants would have against disproportionate impact of the model's reimbursement cuts. The trend factor's importance to the integrity of the model and fair play for participants makes it critical that CMS apply the trend factor appropriately. We ask CMS to clarify that it will use PFS rates to trend the base rates for freestanding RT facilities, and OPPS rates to trend the base rates for hospital outpatient departments.

We also ask CMS to reconsider its proposal to recalculate a trend factor compared to Calendar Year (CY) 2017 rates each year, and instead to calculate a trend factor based on the ratio of CY 2020 to CY 2017 rates for the first two to three years of the model, and then recalculate a trend factor based on the ratio of CY 2022 or CY 2023 rates to CY 2020 rates for the final years of the model. Our concern with the existing proposal is that annual updates based on the most recent year's rates in comparison to CY 2017 could generate significant swings in the trend factor from year to year. RO Model participants would appreciate and benefit from as much stability as possible in the base rates from year to year, which will allow them more certainty when planning practice transformation and innovations in delivery of care without worrying about significant changes in RO Model payments.

Case mix adjustment

CMS also proposes to apply a case mix adjustment to the base rates, which would be calculated based on several variables identified in the Proposed Rule. ACCC supports a case mix adjustment, which will smooth differences between participants and protect against disproportionate impact on certain participants. But we wish to emphasize that providers and suppliers participating in CMMI models, especially mandatory models, highly value transparency, predictability, and simplicity in the calculation of payments under the model. To that end, we believe CMS must provide more detail on how the case mix variables were developed and verified. We also urge CMS to further explain the weight or significance of each of the variables in calculating the case mix adjustment. Finally, we encourage CMS to consider alternative methods of accounting for case mix that would be easier for providers to see and understand, such as the Charlson Comorbidity Index or a percentage of dual eligible patients.

Efficiency factor

CMS proposes to apply an "efficiency factor" to all RO Model participants' historical experience adjustments, which takes the form of a static 0.90 adjustment to the historical experience adjustment for efficient participants and an initial adjustment of 0.90 decreasing to 0.70 for inefficient participants. ACCC does not support the proposal to apply a 0.90 efficiency factor even to efficient participants. As proposed, the "efficiency factor" is simply a 10% reduction in the historical experience

adjustment, which is another critical element of the model that helps to even out and account for differences between participants. There is no reason that efficient participants should receive less than 100% of the historical adjustment, whose intended and appropriate purpose is to recognize that model participants are not beginning at the same baseline. If CMS wishes to recognize participants that have shown efficiency in the past, it must find a means of doing so that does not inherently penalize even efficient participants.

Regardless of whether CMS chooses to adopt our suggestion not to apply an efficiency factor to efficient participants, ACCC recommends that CMS perform the efficiency calculation and reassign participants to the efficient or inefficient categories each year, so that participants that become more efficient over the course of the model are rewarded by removal of the descending efficiency factor.

New technologies

Radiation oncology currently is an area of tremendous technological innovation, with new modalities and new treatment techniques that hold the promise of lifesaving treatment for patients whose cancers are currently untreatable. Yet the Proposed Rule hardly addresses new technologies or how the bundled payments made under the RO Model will allow for the continued development and introduction of new technologies to Medicare beneficiaries who desperately need them. ACCC encourages CMS to consider the following recommendations to allow innovation in radiation oncology to continue flourishing during the model.

We ask CMS to confirm that it will allow newly introduced RT modalities, treatment techniques, equipment, supplies, or other RT items or services to continue to be billed on a fee-for-service basis by not adding new Healthcare Common Procedure Coding System (HCPCS) codes to the list of services and items included in the RO Model bundled payment, if those HCPCS codes were established after publication of the Proposed Rule. This policy would give innovators and model participants alike the confidence that there will be adequate and appropriate reimbursement for new technologies that have gone through the rigorous process of obtaining FDA clearance and Medicare coverage. Innovators already face significant challenges and up-front costs in gathering the data and fostering the provider interest necessary to achieve uptake of a new technology, and we are deeply concerned that such innovation will cease if new technologies are bundled into a payment that may not adequately account for new costs. At a minimum, CMS must ensure that before any new HCPCS code is added to the list of bundled services and items, there is enough data in the Medicare claims to account for the costs associated with the new code.

In the alternative, CMS also could consider establishing a process to apply a new technology add-on to the base rate for participants that demonstrate that they are using new technologies not accounted for in the base rate calculation. This new technology add-on should <u>not</u> be based on a comparison to the use of new technologies by the rest of the nation, as in the novel therapies adjustment under the OCM. Our members who participate in the OCM have consistently told us that the novel therapies adjustment is utterly inadequate to cover the actual costs of the novel therapies they would like to use. This makes it much more difficult for participants to purchase and use new therapies and technologies, which should be the goal of any new technology adjustment. Instead, CMS should calculate any new technology add-on based simply on a reasonable assessment of the additional costs

of using the new technology, and then apply that add-on directly to the base rate, akin to a pass-through payment under the OPPS. Any other approach carries a significant risk of undercounting the costs of using new technologies, forcing RO Model participants (and their patients) to forgo the benefits of those technologies.

Finally, we ask CMS to confirm that it will exclude from the RO Model any Medicare-reimbursable items or services furnished to patients in research studies and clinical trials that are listed on clinicaltrials.gov.

Adjustment for staging

The stage of a patient's cancer at the time of RT planning and delivery has a major effect on the RT modality and, ultimately, on the cost of an RT episode. Depending on the stage, there are likely to be significant differences in treatment approach and cost even within a particular type of cancer. The proposed RO Model would not capture these important differences in cost because it would pay a single bundled rate for each cancer type for each model participant, regardless of the specific patient's staging. This means that RO Model participants that happen to treat a disproportionate number of Stage IV patients, for example, would be paid the same amount as participants that happen to treat a disproportionate number of Stage I patients. Although some of these differences are likely to shake out over time, we believe CMS should consider an appropriate adjustment to the base rate for patients whose cancer is in a more advanced stage. Even if the impact is relatively slight for many participants, the mandatory nature of the model and the significant automatic cuts in payment mean that every additional disadvantage or cut makes it that much more difficult for participants to break even.

New service lines

ACCC encourages CMS to modify the proposed episode payment methodology to take account of situations where an RO Model participant adds a new service line during the term of the model. In such cases, the model participant's historical experience adjustment would be based on the participant's costs before adding the new service line, while the participant's actual costs going forward would include the costs of offering the new service line. This imbalance could dissuade a participant from moving ahead with adopting the new service line, even when there is a need in the community. We encourage CMS to consider adopting a rate review mechanism that participants could ask CMS to use in such instances, as recommended in the comments that ASTRO submitted on the Proposed Rule.

Advance notice of payment rates

CMS proposes that RO Model participants would receive only 30 days' notice of their adjusted payment rates before the beginning of the performance year. We are concerned that this is not enough time for participants to adjust their financial planning to take account of expected payments under the model. We urge CMS instead to align notification of the payment rates with the issuance of the PFS and OPPS final rules, which would give participants closer to 60 days before the beginning of each model year to adjust their financial plans for the year ahead.

II. ACCC urges CMS to phase in mandatory participation in the RO Model to promote an equitable opportunity for success and ensure accurate and useful results from the model.

CMS proposes that the RO Model would be mandatory for the entire five-year term, for all providers and suppliers within specified geographic areas. CMS intends that RT episodes attributed to providers and suppliers in the selected areas would represent approximately 40% of all RT episodes nationally. CMS proposes to select these geographic areas after the RO Model is finalized, that is, in late 2019 at the earliest. As a result, providers that are required to participate would have only a few months to prepare for potentially significant reductions in payment.

As experienced participants in value-based payment systems, we are deeply concerned that a considerable number of the providers and suppliers selected to participate will be unprepared for success or even survival in the RO Model. We urge CMS instead to phase in the mandatory participation requirement to avoid unduly penalizing providers that may want to join the movement toward value-based care but as of today are unequipped to do so, and need time to prepare a plan for transformation and success. To ensure that all RO participants providers selected for the RO Model have a chance to fully participate and succeed in the model, and to ensure that the model generates meaningful data from which CMS can assess performance, we encourage CMS to implement the following changes to the proposed model:

- In the first year of the model, providers and suppliers in the selected geographic areas should be allowed to opt out of participation, and those that do participate should not be required to take on downside risk. In the remaining four years of the model, all providers and suppliers could be required to participate with two-sided risk, or CMS could phase in the level of two-sided risk that participants are required to take on. This phased-in approach would mirror the Comprehensive Joint Replacement model and would be fairer to providers that are unprepared to participate today.

- In the alternative, if the RO Model is mandatory for all participants for the full term, CMS should consider making the model mandatory for a set of providers that accounts for a smaller percentage of national episodes (i.e., less than 40%), at least for the first year, while introducing a voluntary participation option that would allow providers to voluntarily bump up overall participation to a level closer to the desired 40% sample.

- CMS should establish a hardship exemption process, as well as a process for providers and suppliers to voluntarily opt in. These processes will make the rules for participation fairer and increase the likelihood of useful and successful participation for those that do join, without compromising the evaluation of the model's effectiveness. In particular, as noted above, we believe CMS should establish a hardship exemption process for RT providers and suppliers that can show they serve a patient base consisting predominantly of Medicare beneficiaries, given that these providers and suppliers would face disproportionate impact from mandatory participation in the model and would be at a significant disadvantage compared to other participants, not to mention RT providers and suppliers not included in the model. For these and other RO Model participants that would suffer a significant financial hardship from

participation in the model, CMS should allow phased-in participation and/or establish a further adjustment to the base rate to account for this hardship.

We emphasize that our comments advocating a phased-in implementation do not arise from opposition to CMS's larger effort to establish models that will test and hone the effectiveness of value-based payment systems and continue shifting more health care services to payment based on value. Indeed, our members are at the forefront of this movement. In the months leading up to implementation of the OCM, ACCC founded the OCM Collaborative, an online community and resource center for OCM practices to share information about best practices and address logistical difficulties with OCM participation. Currently, 85% of practices still participating in OCM are members of the OCM Collaborative and actively contributing to our common effort to make that model a success. ACCC is committed to encouraging and facilitating cancer centers' participation in innovative payment models, and we look forward to working with CMS to making the RO Model a success as well. But to do that, CMS must not push providers that are wholly unprepared into a model that is mandatory and two-sided from day one.

III. ACCC urges CMS to delay the beginning of the model until no sooner than July 1, 2020.

CMS proposes that the RO Model would begin on January 1, 2020, and seeks comment on an alternative start date of April 1, 2020. Given that providers will not even know if they are participating until November 2019, ACCC believes that either start date would leave all providers – even those that already have significant experience in value-based models – woefully unprepared to participate in the RO Model.

ACCC knows how long it takes to prepare a cancer center to participate effectively in a bundled payment model, because a significant number of our members voluntarily chose to participate in the OCM. Those practices had about a year and a half between the application submission date and the notification of enrollment to prepare their practices for participation in the model, including hiring of new staff, planning for fundamental changes in how their practices are run, training staff and clinicians on these transformative changes, and setting aside funds to pay for these efforts. Even with that significant lead time, most of our OCM practices were not able to fully implement their practice transformation efforts until well into the first year or two of the model. Unfortunately, the overall lackluster financial performance of the model in its first years showed this delayed payoff.

Our members' experience with the OCM makes clear that providers need, at minimum, two years to prepare and transform their practices sufficiently to participate in a bundled payment model. Under the Proposed Rule, however, CMS would give providers in the selected areas just a few months to prepare for participation in the RO Model.

It likely will be even more challenging and time-consuming for providers to prepare for the RO Model than it was to prepare for the OCM. Unlike the OCM, the proposed RO Model includes no monthly supplemental payment to cover the costs of practice transformation. And CMS proposes to make the model mandatory for all providers in selected areas, meaning that providers with little infrastructure to support successful participation in a bundled payment model will be given the same amount of time to prepare as providers that have already made some or all of the necessary

investments to succeed in a value-based system. For example, certain ACCC members that are freestanding RO clinics have expressed that they do not currently have the infrastructure in place to collect and report their performance on the quality measures laid out in the Proposed Rule. Although our members are willing to make the necessary investments if they are chosen for the RO Model, two or even six months is not enough time to make these investments, as our members' experience in the OCM shows. Providers should not suffer significant financial penalties simply because CMS chooses not to give them time to prepare.

We also note that many cancer centers already will have confirmed their intent to participate in an Accountable Care Organization (ACO) or another APM by the time they learn that they must participate in the RO Model. This means that the proposed early start date will impose an especially heavy burden on providers that voluntarily choose to participate in another APM, because they will have to account and prepare for participation in two models, not the one model they had planned on. This is hardly an appropriate policy to apply to providers that are making a voluntary effort and taking the risk of participating in an APM, and we are concerned that it will discourage other providers from taking that risk in the future.

For all of these reasons, ACCC is deeply concerned that CMS's proposed start dates would effectively ensure failure of the model in its first years and would make failure of the model as a whole more likely. If providers have no time to account for bundled payments and make improvements in their practice to adapt, then the model will not be an effective test for innovative payment systems.

We urge CMS instead to start the model no earlier than July 1, 2020. Although this start date would give providers less than a year to prepare (compared to the two years that were required for ramp-up in the OCM), it would ease the inequity of forcing unprepared providers into a mandatory model and help to promote a successful model that gives providers the opportunity to improve, innovate, and help CMS to test the effectiveness of its model. At the same time, we understand and would support a start date for the model at some point during CY 2020 to ensure that the agency can include in the RO Model at least a portion of the claims data from the period during which payment for RT treatment delivery is frozen under the PFS.

IV. ACCC encourages CMS to finalize its proposed exclusion of radiopharmaceuticals and certain brachytherapy surgical procedures from the services covered by the bundled payment.

CMS proposes to exclude certain brachytherapy surgical procedures from the list of services covered by the bundled payment for each RO Model, as well as all radiopharmaceuticals, because these services are not offered in sufficient amounts to allow for evaluation.[2] ACCC strongly supports the proposed exclusions and encourages CMS to finalize them.

[2] *Id.* at 34,500.

V. ACCC encourages CMS to begin a new RT episode when a new course of treatment begins before a pending 90-day RT episode is complete.

CMS proposes that each episode of care under the RO Model would last 90 days from the date of the initial treatment planning service that would trigger the episode. While a 90-day episode may be reasonable for most RT episodes, there are several important and common treatment scenarios where an inflexible 90-day episode would inappropriately incentivize RO Model participants to limit or deny medically appropriate care. We encourage CMS to establish a policy that would begin a new RT episode if a patient begins a new course of treatment before a pending 90-day RT episode is complete.

Our members have alerted us to a number of clinical scenarios in which a 90-day episode would inappropriately include services under a new course of treatment. For example, when treating gynecologic cancers and certain other cancers, it is often most effective and most clinically appropriate for the patient to be treated with both external radiation therapy and brachytherapy. In some cases this combination therapy can effectively cure the patient's cancer, with the brachytherapy used after external therapy to destroy any cancer cells that remain and prevent future metastases, but using external therapy or brachytherapy alone would be inadequate to cure the cancer. But because the course of brachytherapy treatment often begins or takes place entirely within the 90 days after the external treatment, there would be no separate payment for that separate course of treatment under the RO Model.

Another common example of the need for a new episode involves re-irradiation to eliminate bone and brain metastases. By their nature, these cancers are especially likely to recur even after completion of a course of treatment with RT. As a result, it is common for RT providers to deliver one course of RT, then to re-irradiate (using the same or a different RT modality) as little as 30 days later if the patient's cancer comes back. If the RO Model uses a 90-day episode for all cancers, the provider would receive only one bundled payment for the RT services delivered during both courses of treatment, even though these are separate RT treatments for separate occurrences of cancer.

Our members have also cited any scenario where RT is used for palliative treatment, which (in the absence of a separate RT episode payment) likely would discourage palliative use of radiation and lead to higher inpatient hospital admissions. Another example is definitive RT treatment at a primary cancer site, after which the patient is diagnosed with a single site of metastasis and high-dose stereotactic body radiation therapy (SBRT) is indicated. SBRT is a technically labor intensive treatment and often will be performed at a different center. Yet another example is prophylactic cranial irradiation following a patient's complete course of RT treatment in the lung for small-cell cancer. These are not only different sites of treatment but entirely different courses of treatment, with the cranial irradiation furnished separately after the primary treatment of the lung is complete to minimize overlapping side effects.

ACCC is deeply concerned that the proposed RO Model would foreclose these effective and curative treatment options for many patients because model participants simply cannot afford to provide two courses of RT treatment for the price of one. The historical experience adjustment would not address this problem because CMS proposes a single base rate for each type of cancer, meaning that each participant's historical adjustment would include a significant number of episodes where a

second course of treatment during the episode was not appropriate or necessary. In addition, a single payment for two separate courses of RT treatment could be operationally impossible if the two courses of treatment are furnished by different providers. To avoid losing the curative benefits of RT in these cases, we urge CMS to begin a new RT episode when a new course of treatment begins.

We acknowledge that our suggested policy would need to be implemented through a balanced and workable approach that does not introduce excessive complexity to the model. One approach would be to initiate a new RT episode in any case where, during the 90-day term of an initial RT episode, the same or a different RO Model participant furnishes an RT simulation planning service using a computed tomography (CT) scan or other imaging modality. Using Current Procedural Terminology (CPT®)[3] codes 77280, 77285, and 77290 as triggers for a new episode under these circumstances would allow CMS to easily and appropriately identify the beginning of a new episode, because a new simulation planning service is required only when the RT provider is beginning an entirely new course of RT treatment, as in the scenarios described above. The first RT episode would end on the date of that simulation planning service, and the new RT episode would begin on that date and end after 90 days, like any other episode under the RO Model. Although we believe this approach would be workable and would appropriately recognize the additional cost of a new course of treatment during a pending episode, it is not the only possible approach to resolving this important issue, and we encourage CMS to discuss this and other alternatives with stakeholders.

We emphasize that the need to initiate a new course of treatment in these scenarios likely does not indicate that the RT provider's work in delivering the first treatment was inadequate, or that some improvement in the RT provider's practice would result in fewer retreatments in the future. For cancers that are likely to recur shortly after RT is delivered, retreatment in less than 90 days likely means only that the cancer came back and must be irradiated again, which can and does occur for reasons that we do not yet fully understand, regardless of how effectively or efficiently the first course of treatment was delivered. Similarly, a course of treatment with brachytherapy following a course of treatment with external beam RT often is simply what is needed to cure the patient's cancer. If the RT provider nevertheless receives only one bundled payment for both courses of treatment, then the RO Model will create a significant financial disincentive to provide the second course of treatment, even when it is medically necessary and there is nothing the provider could have done to prevent the cancer from recurring. Of course, our members have a professional and ethical obligation to provide necessary care to their patients, so in reality a uniform 90-day episode of care simply means that RT providers who treat a significant number of patients in these clinical scenarios will be disproportionately penalized under the proposed model. Moreover, if CMS does not tailor the episodes of care to the likely pattern and timing of RT treatment for each cancer, the model will fail to effectively capture true differences between RT providers' quality and cost-efficiency in delivering RT services. We look forward to working with CMS to address this issue appropriately in the final rule.

[3] CPT is a registered trademark of the American Medical Association.

VI. ACCC supports the proposed quality measures for the RO Model but encourages CMS to clarify certain aspects of the reporting requirements.

ACCC appreciates CMS's proposals with respect to the quality measures and patient experience measures that RO Model participants would be required to report as a condition of recouping the quality withholding amount. In general, we believe the proposed quality measures are appropriate tools to assess the quality of care and patient satisfaction with the services delivered under the model. However, RT providers need more detailed information about how these measures will be reported and assessed, and we encourage CMS to clarify the following aspects of the Proposed Rule:

- We believe CMS's proposal to require reporting of quality measures for all patients[4] is unduly burdensome and that reporting under the RO Model should be limited to Medicare fee-for-service beneficiaries, consistent with the cohort of patients whose care is covered by the model in the first place. Although collecting data for all patients may be consistent with the measure specifications, it is not consistent with the scope of the RO Model. And, in fact, many of our members believe that it would be more burdensome to set up systems to report quality measures for all patients than for Medicare fee-for-service patients alone. While, in theory, electronic health record (EHR) systems should make it simple for participants to report quality measures in accordance with the measure specifications, often manual collection and reporting will be required because the provider's EHR functionality does not include the required measure, or a patient might have data in multiple EHR systems (physician, hospital, etc.) and these cannot be combined automatically. We urge CMS to reduce the burden of reporting quality measures wherever possible, including by limiting reporting to Medicare fee-for-service patients unless it can be shown that all certifiable EHR systems can report the measure for all patients with minimal or no manual entry required.

- We ask CMS to confirm that providers delivering RT services under contract with hospitals will be allowed to submit quality and patient experience data through the hospital's EHR system. In general, CMS should structure the quality and clinical data reporting mechanisms so that model participants have as much technical and operational flexibility as possible in submitting the required measures and data.

- Our members are concerned that CMS has not provided adequately detailed guidance on the agency's expectations with respect to data collection and submission for the quality measures, especially given the very tight timeframe for implementation of systems to collect and report on these measures. For example, CMS proposes that it would provide participants with "a mechanism to input quality measure data," create a template for participants to complete with the specified numerator and denominator for each measure, and provide a secure portal for data submission.[5] We appreciate CMS's commitment to provide education and outreach to participants on how to use these mechanisms, but CMS's proposed timeframe will leave providers very little time to understand and set up systems to comply with the quality reporting requirements, especially for providers that currently are not reporting these measures. We urge

[4] 84 Fed. Reg. at 34,518.

[5] *Id.* at 34518.

CMS to provide further details on the quality measure collection and submission processes as soon as possible, to give model participants as much time as possible to prepare.

- We encourage CMS to consider enhancing the quality assessment component of the RO Model in the future, for example, by creating an outcomes registry and giving model participants credit toward recouping their quality withholding if they participate in the registry. The registry could measure patient outcomes in areas such as complications, fractures, pain, and hospitalizations. CMS could use the outcomes registries for bone marrow transplantation and CAR-Ts as a model, with appropriate modifications for the specific context of RT. Of course, any reporting or documentation requirements for participation in a registry or any other quality assessment system should be reasonably tailored and not impose an excessive burden on model participants as compared to the likely benefit to patients.

VII. ACCC urges CMS to reconsider the uncompensated burden that would be required to comply with the proposed monitoring and peer review requirements, which are not tied to pay for reporting.

CMS proposes to monitor RO Model participants for compliance with model requirements and for utilization and quality of care, including monitoring for attempts to manipulate the system through patient recruitment and billing practices.[6] Of course, ACCC and its members agree that it is important for providers who are selected to comply with the requirements of the model and to ferret out any manipulation of the model. In particular, to the extent that CMS believes it is necessary to require model participants to participate in a patient safety organization (PSO), we appreciate and support CMS's proposal to require that this PSO be one that collects RO-specific information.

However, we are concerned that the proposed monitoring requirements are excessive and would result in a significant data collection and reporting burden on providers. Moreover, although these data collection and reporting costs are similar to the burdens imposed by the proposed quality reporting requirements, providers would have no opportunity to recoup any of the costs of satisfying the monitoring requirements. Instead, these would be pure costs for model participants. We urge CMS to minimize the uncompensated burden on model participants by finalizing only those monitoring requirements that are truly necessary to ensure compliance with the model and promote high-quality care, above and beyond the proposed quality measures, model rules, and other guardrails that CMS has proposed.

In addition, our members are concerned that the proposed peer review requirements are excessive. The proposed requirements would require peer review for half of a participant's patients as of the very first performance year, with preparation time of a matter of months, regardless of whether the participant has any experience or infrastructure to start from. We believe this proposal would be particularly burdensome on rural and small practices, and we urge CMS to reconsider these requirements, potentially by applying a hardship exemption or phase-in.

[6] *Id.* at 34532.

VIII. ACCC urges CMS to apply the 5% Advanced APM incentive payment to the technical component of RO Model payments as well as the professional component.

CMS proposes to exclude the technical component of all RO Model payments from the "estimated aggregate payment amounts for covered professional services" used to calculate the APM Incentive Payment under the QPP, and to waive the relevant statutory provisions to the extent those provisions would require CMS to include the RO Model technical payments in that aggregate payment amount.[7] This would mean that, even if some part of the RO Model technical payment would be viewed as payment for a "covered professional service" and count toward the participant's APM incentive, CMS would not count that portion when calculating the APM incentive based on participation in the RO Model.

ACCC is deeply concerned about this proposal and urges CMS to work with stakeholders to identify an alternative solution. Although CMS has the authority to waive appropriate statutory requirements under Section 1115A, the APM incentive exists for a very good reason and should not be lightly discarded or discounted. Congress created the incentive to acknowledge that clinicians who enter into Advanced APMs are taking on meaningful shared risk and likely will need to incur significant costs to prepare for and sustain participation in the APM, regardless of whether the clinician eventually earns shared savings or pays shared losses through the model. Although we understand CMS's concern about incentivizing a shift in site of service to take advantage of the APM incentive, we do not believe that justifies discarding a meaningful portion of the incentive payments that clinicians have rightfully earned by participating in an Advanced APM. We encourage CMS not to finalize the proposed waiver and instead to work with stakeholders to find an alternative solution, such as including an appropriate proportion of the RO technical payment in the aggregate payment amount for the APM incentive, based on a reasonable estimate of the amount of that technical payment that would be included for the APM incentive calculation if payments were not bundled under the RO Model.

IX. ACCC encourages CMS to structure the final RO Model so that all RO Model participants will be qualifying participants in an Advanced APM for purposes of the QPP, assuming minimum participation requirements are met.

The Proposed Rule explains how CMS structured the proposed RO Model to meet each requirement of the definition of an Advanced APM, which would allow eligible clinicians selected to participate in the RO Model to be exempt from adjustments under the Merit-Based Incentive Payment System (MIPS) and earn the 5% APM incentive, assuming that the clinician meets the minimum-payment or minimum-patient threshold under the QPP regulations.[8] Specifically, CMS explains that the RO Model would require each participant to use certified EHR technology (CEHRT) (including at least 75% of individual eligible clinicians in an APM entity); to have part of payment for services under the RO Model depend on the participant's performance on eligible quality measures; and to require participants to bear more than a nominal amount of risk.

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[7] *Id.* at 34525.

[8] *Id.* at 34522-24.

If the RO Model is structured largely as proposed, then participation will be a significant, risky, and costly undertaking for providers in areas that are selected to participate. Our members also hope that it will be a positive and productive effort. To make that hope a reality, however, providers that are required to participate in the RO Model should have every possible assurance that their participation will qualify them for exemption from MIPS and will earn them the APM incentive for participation in an Advanced APM. Although we understand that CMS cannot guarantee that providers will meet the minimum payment or patient volume requirement to be a qualifying participant, the agency should finalize a structure that squarely satisfies each of the requirements for an Advanced APM.

We also ask CMS to clarify that the requirement for RO Model participants to use CEHRT means CEHRT certified to the 2015 edition standards.

X. ACCC encourages CMS to open the RO Model to voluntary participation by Medicare Advantage plans and other payers.

CMS proposes to limit the RO Model to RT episodes that otherwise would be paid under Medicare fee-for-service and does not propose to coordinate the model with Medicare Advantage plan sponsors or commercial payers. ACCC believes that limiting the RO Model to Medicare fee-for-service would miss an opportunity to allow as many providers and payers as possible to explore and assess innovative approaches to delivering care under a bundled payment model. Although we understand that CMS does not have the authority to require Medicare Advantage organizations or other payers to join the RO Model or implement similar bundled payment systems, we do not see any reason why CMS should not open the RO Model to voluntary participation by these other payers, which would be consistent with policies that CMS has adopted, for example, in the OCM, where other payers had the opportunity to voluntarily adopt analogous bundled payment systems in conjunction with the CMS-sponsored model.

XI. ACCC asks CMS to clarify how the RO Model will overlap with the OCM in a manner that allows for full and fair participation in both models.

CMS proposes a high-level approach to coordinating payment when an RT episode subject to the RO Model overlaps in whole or in part with a six-month chemotherapy episode under the OCM. CMS proposes that the bundled payments made to RT providers under the RO Model would be counted toward the total cost of care in the OCM episode, but without deducting the discount or withholding amounts that in fact would be deducted from the RO Model payment. CMS states that this is to avoid counting those withholding amounts as savings under the OCM and to avoid paying the withholding amounts twice.

We believe it would be more appropriate and fairer to providers participating in both models to use the actual (discounted) amount of the RO Model base payment as the payment to the provider for purposes of the OCM cost calculation. We disagree that doing so would improperly double-count savings or result in improper double payment. With respect to the discount, providers receive no financial credit under the RO Model for adjusting their spending to make do with lower reimbursement, so there is no double-counting of savings if that discount is also included in the OCM calculation. With respect to the withholding, there is no guarantee that RO Model participants will earn

those amounts back after reconciliation; even if they do, it likely will not be without the participant incurring other costs to comply with quality reporting requirements. The fairer and more accurate approach would be to deduct the discount amount from the OCM calculation, and to deduct the amount of withholding that is not regained through quality performance. To the extent that there are considerations that weigh in favor of deducting the discount and withholding from the OCM total and considerations that weigh in favor of not deducting them, we believe CMS should err on the side of deducting them, keeping in mind that OCM participants voluntarily entered into an APM without knowing that they would be required to accommodate mandatory participation in another APM with very little time to adjust or plan for the additional risk that they must take on as a result.

We also ask CMS to confirm that the OCM targets for overlapping episodes will not be affected by the discount and withholding under the RO Model. If providers are forced to adjust to a significant cut in reimbursement under the RO Model (through the discounted bundled payment), they should not then be forced to adjust to the same cut in reimbursement all over again under the OCM (through a reduction in the target cost). This would be especially unfair – and inappropriately skew the results of the OCM – if CMS were to finalize its proposal not to account for the deduction in the total costs for an OCM episode.

Finally, we seek additional clarification of how CMS would implement the proration of RO Model payments for RT episodes that only partially overlap with OCM episodes. CMS proposes simply to prorate based on the number of days of overlap and – as noted above with respect to fully overlapping episodes – to assume that all withholds are eventually paid. Although this approach may be less operationally complex for CMS, it risks unfairly denying payment to providers that have earned higher payments under the established rules of the OCM.

We urge CMS to reconsider its proposals with respect to the overlap between the RO Model and the OCM and to finalize policies that allow providers to fully and fairly participate in both models.

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ACCC greatly appreciates the opportunity to comment on the proposed RO Model. ACCC reiterates our commitment to promoting access to effective cancer treatments for all Medicare beneficiaries who need them, including through carefully structured value-based payment models. We hope CMS will consider our comments above and those of other stakeholders representing RO providers and suppliers and make appropriate changes to the proposed RO Model to ensure that it offers a real opportunity to promote and test innovative approaches to delivering RT without compromising the best interests of Medicare beneficiaries.

If you have any questions about our comment letter or would like to discuss our comment in further detail, please contact Christian Downs, ACCC's Executive Director, at cdowns@accc-cancer.org or 301-984-9496.

Respectfully Submitted,

Ali McBride PharmD, MS, BCOP
President, Association of Community Cancer Centers