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Submitted electronically to: http://www.regulations.gov and sent via email

August 10, 2021

The Honorable Xavier Becerra, Secretary Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20201

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

Elizabeth Fowler, Ph.D., J.D., Deputy Administrator and Director Center for Medicare and Medicaid Innovation Centers for Medicare & Medicaid Services United States Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244

Re: Preliminary comments on Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies [CMS-1751-P] and the Radiation Oncology Model [CMS-1753-P]

Dear Secretary Becerra, Administrator Brooks-LaSure, and Deputy Administrator Fowler:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are submitting this letter as preliminary comments on aspects of both the Medicare Physician Fee Schedule proposed rule for 2022 ("Fee Schedule") and the Radiation Oncology Model ("RO Model") proposal contained in the Hospital Outpatient Prospective Payment System proposed rule for 2022 ("HOPPS). The reason for these preliminary comments is to express our deep concern about severe Medicare payment cuts and the implementation of a mandatory radiation payment model during the raging public health emergency ("PHE").

These new Medicare payment cuts to oncology medical services, diagnostic imaging, and radiation therapy, as well as the scheduled implementation of the RO Model on 1/1/2022, could not possibly come at a worse time. Independent community oncology practices are once again fighting to keep their doors open to treat Americans with cancer as hospitals in many areas are overrun with cases of the COVID Delta variant. According to the Washington Post's rolling seven-day average, the nation is already experiencing more than 100,000 cases of COVID a day, an increase of 42.1% over the past week in new daily reported cases. And the highly contagious Delta variant could result in an increase

¹ https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/

to 300,000 new cases of COVID per day during August, according to the University of Washington's Institute for Health Metrics and Evaluation.² At a time when our government should be asking us how it can help and doing everything in its power to support community oncology practices during the PHE recently extended by Secretary Becerra, we are faced with a seemingly tone-deaf Department of Health and Human Services ("HHS"), its Centers for Medicare & Medicaid Services ("CMS"), and the CMS Innovation Center ("Innovation Center").

For the reasons we summarize in this preliminary comment letter, we request that CMS immediately forestall any Medicare payment cuts and implementation of the RO Model. We find it especially troubling and disconcerting that HHS/CMS appears to be blind to what is happening with the dramatic shortfalls in cancer screenings resulting in Americans delaying screenings and then presenting with more advanced cancers when diagnosed. These are extraordinary times that require extraordinary measures by HHS/CMS to protect the lives of Americans with cancer during the resurgent pandemic. The Medicare payment cuts and RO Model implementation are endangering the backbone of the nation's cancer delivery system – independent community oncology practices – which has proven its mettle during the pandemic. And, as such, you are endangering the lives of Americans, especially seniors, with cancer.

As background, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. We are the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA's mission since its grassroots founding close to 20 years ago has been to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status. To that end, we are dedicated to advancing oncology payment reform that enhances the quality of cancer care for all, achieves health equity, and controls costs.

Independent community oncology practices have kept their doors open and facilities COVID free to treat Americans with cancer while the pandemic ravaged the country and forced hospitals to deal with treating patients with the virus. The Herculean efforts of these practices across the country proved their value as the foundation of the nation's cancer care delivery system. The emotional and financial pressures oncologists and staff have faced during these challenging times have been enormous. We optimistically believed that we were seeing the light at the end of the tunnel of this pandemic, but the spread of the Delta variant of the virus has created another wave of COVID. We are very concerned that screening shortfalls will worsen with this resurgence, resulting in even more patients presenting with advanced cancers. This will put additional pressures on independent community oncology practices, especially as hospitals in many areas of the country have to dedicate their resources to treating patients with COVID. The HHS/CMS payment cuts and planned implementation of the RO Model are simply adding to those pressures and the strain on our nation's community oncology practices.

What follows are preliminary comments supporting our concerns about the proposed Fee Schedule payment cuts and implementation of the RO Model. The comment letters we will submit before the filing deadlines for both the Fee Schedule and HOPPS proposed rules will contain more detailed comments.

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https://www.washingtonpost.com/health/2021/07/31/when-will-covid-cases-drop/?mkt_tok=ODUwLVRBQS01MTEAAAF-pcrhD3dfsnWGSV72rNWVa08hLFYT4vl7vRjTRLfHnu5dwYAgu8TFbBHhg16u86yZRjB4ufvuBunQRJojKIsK8LOWDhXBHdm0rTkxBpdlcIiX

The Fee Schedule Payment Cuts are Deceptive and Excessive.

In the Fee Schedule, CMS states that the payment cuts to "Hematology/Oncology" will be two percent, to "Radiology" will be two percent, and to "Radiation Oncology And Radiation Therapy Centers" will be five percent. However, our preliminary analysis using actual oncology practice data finds that the payment cuts will be more severe as follows:

•	Evaluation and Management	1.8 percent payment cut
•	Drug Administration	14.8 percent payment cut
•	Imaging	9.3 percent payment cut
•	Radiation Therapy	9.9 percent payment cut

We note that the payment cuts stated by CMS are actually larger because of the one-year 2021 conversion factor increase of 3.75 percent granted by Congress in the Consolidated Appropriations Act of 2021. CMS is understating the impact of the cuts with the comparison to 2020, not 2021, with the 3.75 percent conversion factor increase. Additionally, we are using actual practice data to determine the payment cuts to independent community oncology practices for these essential services.

These payment cuts could not come at a worse time in terms of practices dealing with the pressures of the resurging COVID crisis due primarily to the Delta variant of the virus. We find it very difficult to comprehend that HHS/CMS cannot understand that these payment cuts, followed by years of misguided policy regulations, simply put more pressure on independent practices to merge with increasingly large hospital systems. What that does is simply increase the costs to Medicare and seniors due to the higher costs found in the more expensive hospital setting.

COA is Adamantly Opposed to Mandatory Models, Including the RO Model.

By definition, mandatory models are not collaborative. They are government-designed models that are forced on providers. As we have repeatedly expressed, COA is more than ready, willing, and able to work with the Innovation Center in developing models that are realistic and viable in their design to lower costs while enhancing the quality of cancer care. However, models that are simply designed with a "stick" in mind are not viable but must be forced on providers. Models must have both a "carrot" and a "stick" that are in balance to achieve robust provider participation.

In addition to the above, COA is opposed to mandatory Innovation Center models for the following reasons:

- The mandatory models proposed by the Innovation Center typically involve a large percentage of the country. They are contrary to the statutory intent of the Innovation Center charter. They are not a way of testing and building on "phase 1" models but are simply a way of bypassing Congress and existing law to reduce Medicare spending for a large percentage of the country. This is dictatorial not innovation derived through stakeholder collaboration.
- Mandatory models are forced experiments on patient care, but without any of the safeguards of clinical research. They force providers to alter care patterns in concert with model design. This is opposed to voluntary models where providers agree to participate in models where they will not be restricted in clinical decision making, even if they are exposed to downside risk.
- We note that mandatory models will not help address racial, ethnic, and socioeconomic health disparities. They
 will, in fact, exacerbate the problem of disparities. Access to care may be severely limited and inequitable
 with mandatory models, especially to the most disadvantaged patients with cancer exposed to health disparities.

- Mandatory models split practices with multiple locations into sites that are forced to participate and those left out of the model. This is certainly true of the RO Model. This complicates everything from clinical standardization within the practice, care coordination within the practice, and billing operations. Mandatory models simply add undue pressure and costs on practices, exactly at the worst time in the current PHE.
- Mandatory models for practices that compete against exempt hospital systems are particularly disadvantaged in these programs, especially the 11 dedicated cancer hospitals with Medicare payment exemptions that spend their increased revenue from Medicare reimbursement to further grow their footprint. We note that these 11 dedicated cancer hospitals are exempt from participating in the RO Model.

In relation to the proposed RO Model, we specifically note the following:

- Attached is our comment letter on the initial proposal of a Radiation Oncology Model. We call your attention to the recommendations made by COA, which have fallen on deaf ears at the Innovation Center. There was no questioning of our recommendations or even an attempt to understand them. Once again, this is not collaboration. This is the nature of mandatory models.
- Please note in the original comment letter our statements regarding the unconstitutional nature of mandatory models. Even in the proposed RO Model, it is clear this is not a "phase 1" test of a model but a change in Medicare reimbursement that simply end-runs the Congress.
- CMS notes in the proposed RO Model that group practices will see a payment increase while hospital outpatient departments will see a decrease over the five-year span of the model. We note that the stated increase is also deceiving because it does not include the two percent sequester cut and does not account for the Fee Schedule decrease in payments for radiation therapy. The net impact, even if CMS is correct in its estimate of the slight payment increase to practices, will be a reimbursement cut to independent community oncology practices that have therapeutic radiation.
- The RO Model proposed during this new COVID crisis is both poor experimental design and potentially dangerous. We say that because you are proposing to introduce the model during a time when there is a huge confounding variable in the COVID resurgence. Who knows if the Delta variant will subside or if we will face the Lambda or another COVID variant, especially a variant immune to available vaccines? Additionally, forcing any oncologist to rethink treatment based on payment changes/restrictions can potentially be very harmful to patients, again, at this critical time.

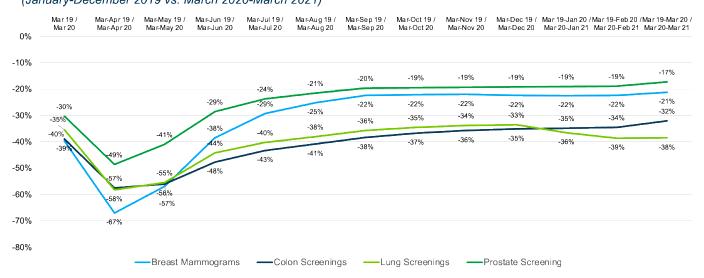
Community Oncology Practices are Inundated with COVID-related Clinical and Operational Issues. They Need Help, Not Payment Cuts at This Critical Time.

Given that you may not be willing or able to travel outside of Washington D.C. to visit a community oncology practice, we will gladly set up a Zoom meeting for you to hear from oncologists and practice administrators. We respectfully say that you simply do not understand the realities of the myriad of challenges facing community oncology practices. If you did, you would be asking practices what the government could be doing to make sure all Americans, regardless of race, ethnicity, or any socioeconomic factors, are being screened for cancer and receiving timely treatment close to home. Instead, the proposed payment cuts to cancer care and burdening practices with a mandatory RO Model threatens the already pressured and fragile backbone of the nation's cancer care delivery system, especially at a time when hospitals across the country are overwhelmed again with COVID patients.

Here are just some of the challenges that practices are now facing:

- Finding clinical and operations staff has been very challenging. Practices report individuals applying for
 positions but then cancelling interviews at the last moment. All types of businesses have reported trouble
 finding staff, and the same is true for community oncology practices.
- Compounding this problem in finding staff is the dilemma practices face in whether to mandate that staff get vaccinated. As you know, cancer patients in active treatment are most often very immunocompromised and, therefore, highly susceptible to infection. However, practices that mandate staff be vaccinated face situations of unvaccinated staff quitting or not reporting to work.
- Oncologists have reported that patients are presenting with more advanced cancers because of delays in getting screened. As you will see from the graph below, screenings for breast (-21 percent), colon (-32 percent), lung (-38 percent), and prostate (-17 percent) cancers are dramatically down as of March 2021 as compared to pre-COVID levels.³ This is extremely alarming because cancers are going undiagnosed. The immediate impact of patients presenting with more advanced cancers is troubling, as are the likely longer-term effects on morbidity and mortality. In order to help promote cancer screenings, COA has launched a major PSA campaign *Time to Screen*⁴ with Grammy Award-Winning artist Patti LaBelle as a spokesperson. We are especially concerned how this screening shortfall has adversely and inordinately affected Americans along racial, ethnic, and socioeconomic lines.

Relative Change in Billing Frequencies for Select Cancer Screening Services (January-December 2019 vs. March 2020-March 2021)



Recommendation

Given the dire circumstances with the Delta COVID variant, CMS should enact its proposed Extreme and Uncontrollable Circumstances (EUC) policy for the RO Model and push back the implementation of the model to 1/1/2023. The Delta variant is affecting most parts of the country. In fact, in analyzing the distribution of the RO Model mandated participants by zip codes, 43 percent of the RO Model zip codes are above the median number of the COVID case rate.

³ Avalere Health and COA analysis of Inovalon Provider Clearinghouse data. Note: Claims on average represent 5-7 of Medicare FFS nationally and include CMS-1450 claims from Institutional providers and CMS-1500 claims from Non-Institutional or Professional providers.

⁴ http://www.Timetoscreen.org

In response to reviewing this letter, Dr. Debra Patt, a practicing oncologist, COA Director and Officer, summed up the situation all too well, "I think it is hard to express the increased burden in our clinics – the extra time it takes to tell people about their cancer, their prognosis, their treatment when they are alone, to advise them about COVID precautions and what they can and cannot do, to discuss vaccination, and then the anxiety and depression that are heightened as cancer patients face this journey singularly. I feel like non-clinicians really don't understand how difficult it has been and continues to be. Again, this is not the time to significantly alter the status quo!"

Given President Biden's longstanding commitment to cancer, both its cure and care, it is very difficult to comprehend how his Administration is proposing severe Medicare payment cuts to cancer care and implementing an RO Model in the middle of a raging pandemic. Once again, this should be a time when his Administration, above all prior administrations, should be reaching out to support independent community oncology practices, not subjecting them to harsh and unnecessary measures.

We stand ready to discuss this letter in greater detail and answer any questions.

Sincerely,

Kashyap Patel, MD

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President

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Executive Director

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CC: Hon. Richard Neal, Chair, House Committee on Ways and Means

Hon. Frank Pallone, Chair, House Committee on Energy and Commerce

Hon. Ron Wyden, Chair, Senate Committee on Finance

Hon. Kevin Brady, Ranking Member, House Committee on Ways and Means

Hon. Cathy McMorris Rodgers, Ranking Member, House Committee on Energy and Commerce

Hon. Michael Crapo, Ranking Member, Senate Committee on Finance



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September 13, 2019

Submitted electronically to: http://www.regulations.gov

The Honorable Seema Verma, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CAG-00451N P.O. Box 8013 Baltimore, MD 21244-8013

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

Dear Administrator Verma:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we are submitting this comment letter regarding the Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures – Radiation Oncology Model (CMS-5527-P, referred to herein as the "RO Model").

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA's mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For more than 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

We appreciate the Centers for Medicare and Medicaid Services' (CMS') decision to issue a model focused on radiation oncology. We support CMS' effort to transition providers out of fee-for-service arrangements and into value-based care solutions that will improve quality of care, lower costs, and enhance patient experience. Value-based care solutions via alternative payment models (APMs) create opportunities for different providers to participate and succeed in unique and dynamic arrangements. The RO Model will fundamentally shift physician reimbursement and incentivize appropriate and timely care. We appreciate CMS' commitment to increasing the number of APMs for providers to join and increasing the number of specialty focused APMs.

While we are pleased that CMS is moving in the direction of value-based care, we have significant concerns regarding some of the RO Model parameters. We are concerned that the agency's proposed model will create unnecessary burdens and challenges to physicians. Specifically, our concerns are as follows:

- Mandatory Nature and Scale of the RO Model
- Timing of the RO Model
- Base Rate Methodology
- Episode Stratification and Flexibility
- Discounts, Operations, and Cash Flow Disruption
- Quality Measures and Overlap with Other Models
- Reconciliation Process

We will provide detailed comments on each of these areas in this letter.

Mandatory Nature and Scale of the RO Model:

COA supports the creation and testing of Alternative Payment Models (APMs), particularly Advanced APMs and MIPS APMs, through the CMS Innovation Center (CMMI). However, we are concerned with the mandatory participation element of the RO Model. In general, we do not believe mandatory models are appropriate given the operational challenges associated with joining and participating in an APM. It is important to give providers the choice to join an APM because not all providers have the infrastructure, commitment, and organizational buy-in to succeed in new payment arrangements. If required to participate, providers may not have adequate support to achieve the model's desired goals while ensuring they continue to meet the needs of their patients.

As we have detailed in the past, COA believes that mandatory demonstration projects are not in the charter of CMMI as written into law by Congress. While CMMI is meant to serve as an incubator for payment and delivery reform ideas, it should not implement models that fundamentally and effectively change Medicare reimbursement policies.

The RO Model, as proposed, is another complex and transformative demonstration developed by CMMI, with potentially broad geographic reach and strong potential to disrupt the cancer care delivery system. COA is **staunchly opposed** to <u>mandatory</u> models, especially of the scale and complexity outlined as part of the RO Model. The RO Model establishes a "demonstration" of the size and scope that far exceeds anything that can be reasonably considered a "test."

COA's legal and constitutional reasons for our opposition to <u>mandatory</u> CMMI demonstration projects are summarized as follows:

• The RO Model as Proposed Exceeds CMS' Statutory Authority. In mandating a model, CMS will undoubtedly rely on Section 1115A of the Patient Protection and Affordable Care Act ("ACA"). The RO Model as proposed exceeds CMS' authority because, among other reasons: (A) the RO Model is inconsistent with the express mandate of Section 1115A; (B) the RO Model – by being

<u>mandatory</u> in scope and potentially affecting a large portion of the nation – is not a test or model; and (C) the RO Model appears not to be based upon a model developed by CMMI, but rather one developed outside of CMMI.

- The Secretary¹ Has No Authority to Waive Medicare Provisions Under the RO Model. As the RO Model fails to meet the requirements for "testing," the Secretary has no authority to waive any requirements of the Medicare statute.
- The RO Model Contravenes Other Applicable Laws. The RO Model violates Section 3601 of the ACA, as the implementation of the model would affect guaranteed Medicare benefits and other provisions.

It is important to note that other models, such as the Bundled Payments for Care Improvement Advanced (BPCI Model) and the Oncology Care Model (OCM), are voluntary models and have significant provider interest and participation. As such, we believe models do not need to be mandatory in order to garner interest and participation. The RO Model fundamentally restructures the reimbursement model for radiation oncologists, so it is vital for CMMI to first test the model – as a true *test* – and collect data on results prior to considering a larger scale model, certainly one that is far reaching and mandatory.

COA is also concerned with the scale of the RO Model. CMS proposes to include 40 percent of all episodes nationwide and 17 cancer types in the model. We believe this is excessive. Radiation oncologists first need to understand the mechanics of the model on a smaller scale prior to any large-scale implementation. As such, if CMS continues with a mandatory model, we urge CMS to consider testing the RO Model on a smaller scale with fewer participants and cancer types and then analyze performance data prior to an increase in scope.

CMMI should be working closely with COA and other organizations to develop the RO Model into one that will first test and then implement the model on a broader scale. We strongly believe that no provider should be forced into any transformative model.

Recommendation:

• We recommend that CMS make the RO Model a voluntary program for radiation oncologists. In addition, we recommend that CMS reduce the number of cancer types included in the model and instead collect and analyze performance data prior to any large-scale implementation.

Timing of the RO Model:

Participation in alternative payment models is both challenging and time consuming. Practices need to invest time and resources prior to the start of the model and continue to do so throughout their participation in order to achieve success. COA is concerned that the proposed start date of the RO Model does not give practices enough time to make the necessary practice transformation changes and will therefore result in many operational challenges for radiation oncologists. Furthermore, because this model restructures

¹ For purposes of the statute, "Secretary" is defined as the Secretary of Health and Human Services, "except when the context otherwise requires." 42 U.S.C. § 1301(6).

reimbursement for physicians there will need to be additional time to understand the implications of this change.

Recommendation:

• Instead of having the model start on January 1, 2020, we recommend that the model start on August 1, 2020. To create the most efficient and effective rollout and start to the RO Model, CMS must give providers more time to understand how the model will affect their practices and what investments must be made in order to succeed in the model.

Base Rate Methodology:

COA appreciates CMS' detailed methodology for calculating the professional component (PC) and technical component (TC) payments to radiation oncologists. However, for this model to succeed, it is vital to set accurate and appropriate rates which ensures the reimbursement is accurate for all providers, regardless of the site of care in which they practice.

COA's primary concern with the base rate methodology is the use of Hospital Outpatient Department (HOPD) episodes only. According to CMS' analysis, HOPDs furnished 64 percent of episodes nationwide from January 1, 2015, to December 31, 2017. Although HOPDs furnished the plurality of episodes, CMS' methodology does not include all episodes, which weakens the overall structure of the RO Model. Furthermore, CMS' analysis suggests that PFS episodes utilize IMRT to a greater extent, however the claims analysis provides no basis to suggest that such utilization is not medically necessary.

We appreciate CMS' inclusion of the Outpatient Prospective Payment System (OPPS) and Physician Fee Schedule (PFS) trends in the trend factor calculation; however, given our experience with the OCM, we remain concerned about the utilization of a trend factor in general, and seek to ensure that the base rates are updated in a manner that fully accounts for changes in the cost of care. We believe it is important for the base rate methodology to also include OPPS and PFS episodes because it will create more accurate and fair payments prior to the application of the trend factor in the payment methodology.

Recommendation:

• Instead of calculating base rates on HOPD episodes only, we strongly recommend that CMS also include PFS episodes. By including all episodes (i.e., HOPD and PFS episodes) in the base rate calculation, CMS will include a greater patient population which will in turn reflect more accurate payments to physicians. In addition, by revising the base rate calculation, CMS will account for different care patterns based on a greater patient mix, which will create more fair and appropriate payments to physicians.

Episode Stratification and Flexibility:

COA acknowledges and appreciates CMS' commitment to innovative payment arrangements in Medicare. However, we are concerned with the proposed capitated arrangement. Specifically, we believe that the capitated system creates a lack of flexibility for different practices with different patient populations. It is important for CMS to consider the stages of diseases for different cancer types when calculating payments to physicians.

Recommendation:

• Because there are notable differences in the treatment approach for patients with stage 1 cancer versus stage 4 cancer, we recommend that CMS create different payments based on a practice's patient risk levels. Although CMS adjusts the base rate for a physician's historical case mix, the model does not set separate reimbursement rates for different types of patients. Like the OCM, we recommend that CMS create a "high-risk" and a "low-risk" cohort for certain cancer types (e.g., breast, prostate, and lung). By stratifying within cancer types, CMS will create more accurate and fair payments to physicians.

In addition to appropriate stratification, we believe it is important to create a flexible model that accounts for changes in the health care system. Importantly, CMS must consider how to account for changes in technology and innovation in radiation oncology.

Recommendation:

• We urge CMS to ensure that the RO Model does not stop new techniques and approaches to treatment from being utilized simply because it is not accounted for in the payment methodology. To account for new techniques and treatment approaches, CMS could take a similar approach to the novel therapy adjustment (NTA) in the OCM. Under this approach, CMS could calculate average spending for a new treatment (or a new application of an existing advanced radiotherapy technique) and if a practice spends more than a comparison group, the difference could be included in the Professional Component (PC) and Technical Component (TC) payments.

Discounts, Operations, and Cash Flow Disruption:

In addition to all the withholds, CMS proposes a 5 percent TC discount. We believe the 5 percent TC discount serves policy purposes beyond guaranteeing savings for CMS. Radiation oncology facilities incur significant capital costs in establishing and maintaining state of the art radiotherapy technology (including vault construction, radiation shielding, equipment servicing), we believe the 5 percent discount will only create more challenges for physicians. Discounting technical payments may adversely impact quality of care and is not consistent with the goals of this model. Radiation oncologists must have an appropriate flow of payments to operate and maintain technology needed to help patients and improve outcomes. There are several examples of technologies that radiation facilities employ which are critical for patient care. Facilities rely on technical payments to invest in these technologies, which actually increases the value of care by decreasing long term toxicity to patients. A prime example is the utilization of deep inspiration breath hold technology to significantly decrease risks of late cardiac toxicity in patients undergoing breast radiotherapy.

Recommendation:

• We recommend that CMS eliminate the 5 percent TC discount because it may otherwise have severe adverse consequences on radiation therapy centers, especially those who serve a disproportionally large Medicare population, particularly in underserved and rural areas.

For providers to succeed in this model, CMS must provide frequent data to participants. We believe it is important to receive data on a regular basis so participants can track patients, analyze performance, and identify opportunities for improvement.

Recommendation:

We recommend that CMS provide RO Model participants data on a monthly basis. Participants in
other models, such as BPCI Advanced, receive monthly data feeds and we believe this should be
the standard for all APMs. If CMS would like providers to take on more risk at a quicker pace, it
is important to provide as many resources to participants as possible and consistent data is one
resource that can result in notable and impactful change.

CMS proposes to withhold a portion of the base rate for interrupted/incomplete episodes (2 percent withholding for the PC and TC). Although we understand CMS' rationale for withholding payments upfront, we believe that by splitting payment at the beginning and end of episodes, physicians will already need to manage their finances to ensure appropriate cash flow. As such, we are concerned that further reducing these payments will create unnecessary burdens for providers. Many providers will not have the cash flow necessary to wait until reconciliation to receive these payments.

In addition, we are concerned with the 1 percent TC withholding for patient experience beginning in performance year three. Patient experience is based on surveys that are mailed out and have varied response rates. For many practices, especially those in rural areas or with a lower socioeconomic patient population, patient experience surveys do not adequately capture performance. As such, we believe that a 1 percent withholding is unreasonable and should only serve as supplemental data collection.

Recommendation:

• We recommend that CMS eliminate the 2 percent interrupted/incomplete episode withholding because prospective payments are already split at the beginning and end of episodes. In addition, we recommend that radiation therapy's Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data be collected as supplemental data for at least one year prior to any withholdings associated with patient experience.

Quality Measures and Overlap with Other Models:

COA supports the inclusion of quality measures in APMs. We believe it is important to incorporate quality guardrails and measurements to ensure the delivery of high-quality care. Generally, we support CMS' proposed quality measures; however, because patients already receive survivorship care plans, we believe the CMS quality measure for a care plan is duplicative and should be considered for modification or removal. CMS is focused on streamlining quality programs and focusing on a smaller number of meaningful measures and we believe modifying or removing this measure provides an opportunity to support CMS' goal. COA also supports measures and processes that reduce the administrative burden for practices. Typically, models require practices to keep records for 10 years; however, to create less administrative burden for practices, we believe practices should only be required to keep records for 6 years.

Recommendation:

• We recommend that CMS either remove or modify the care plan quality measure to remove duplicative processes. To alleviate provider burden, we also recommend that CMS require practices to keep records for only 6 years.

With the creation of more APMs, CMS must consider how these models will interact with one another and what this means for participation in different models.² Oncologists, including radiation oncologists, are eligible to participate in the OCM, which is similarly focused on oncology care. Providers participating in the OCM have already invested in practice transformation, including learning about the model, modifying care processes, and navigating successes and challenges. CMS would like to transition as many providers to APMs as possible. Therefore, CMS should focus on supporting providers currently not participating in an APM and encouraging these providers to participate, rather than requiring some providers to participate, in a second model, especially without any clarity on how these models may interact. We support CMS' goal to transition providers to risk-bearing programs and believe CMS will most effectively achieve this goal by focusing on providers not currently participating.

Recommendation:

• We recommend that CMS exempt OCM practices from participating in the RO Model. Greater clarity is needed on how such models may interact before mandating organizations and providers participate in multiple models.³ Instead, we encourage CMS to find ways to encourage providers currently not in an APM to join new payment models.

Reconciliation Process:

COA appreciates the opportunity to review reconciliation results and submit potential errors to CMS. However, we are concerned that a 30-day window for review and submission is insufficient to fully understand the details of the reconciliation report, assess potential errors, and work with CMS to address potential errors. In addition, COA is concerned that the true-up process unnecessarily extends the process and could create potential cashflow issues for practices.

Recommendation:

• To give practices additional time to review data and to not interfere with cash flow mechanisms, COA recommends that CMS provides a 90-day period for practices to review their reconciliation data and file an error report to CMS. In addition, COA recommends eliminating the true-up process and adhering to the reconciliation process given that most claims are submitted and completed within a reasonable timeframe relative to the episode of care.

Conclusion

COA appreciates the opportunity to comment on this proposed radiation oncology APM and looks forward to discussing it with you further. We are extremely willing to work with the administration to

² Press MJ, Rajkumar R, Conway PH. Medicare's New Bundled Payments: Design, Strategy, and Evolution. JAMA. 2016;315(2):131–132. doi:10.1001/jama.2015.18161.

³ Mechanic, R. When New Medicare Payment Systems Collide. NEJM. 2016; 374:1706-1709, DOI: 10.1056/NEJMp1601464.

ensure the final RO Model is appropriately flexible for patients and qualified providers, including community oncologists, and that it results in high-quality, low-cost care, and enhanced patient experiences for all patients included in the model.

Please do not hesitate to reach out with any questions.

Sincerely,

Anshu Jain, MD

Chair, COA Radiation Therapy Task Force

Michael Diaz, MD

President

Ted Okon

Executive Director