September 16, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8013

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

Dear Administrator Verma:

The American College of Radiology (ACR), representing more than 36,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the Specialty Care Models, specifically the Radiation Oncology (RO) Model, to Improve Quality of Care and Reduce Expenditures.

In this comment letter, we address the following important issues:

- Model Performance Period
- Mandatory Model Design
- RO Model Episodes
- Included Services
- Included Modalities
- Included Cancer Types
- Multiple Disease Sites
- Episode Payment Construct
- Site-Neutral Payments and National Base Rate Development
- Discounts and Withholds
- Recognition of 2020 and 2021 MIPS Performance Bonus Payments
- Quality Measures
- Clinical Data Collection
- Monitoring for Compliance
- Local Coverage Determinations
- The RO Model as an Advanced Alternative Payment Model

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Model Performance Period

Proposals

CMS proposes to test the RO Model for 5 payment years (PYs). CMS proposes to define the "model performance period" to mean January 1, 2020, the date the Model begins, through December 31, 2024, the last date during which episodes under the Model must be completed. Alternatively, CMS is considering delaying implementation to April 1, 2020 to give RO participants and CMS additional time to prepare. An April 2020 start date would only affect the length of payment year (PY) 1, which would be 9 months. All other PYs would be 12 months. For all episodes to be completed by December 31, 2024, no new episodes may begin after October 3, 2024.

CMS invites public comments on the proposed model performance period and potential participants' ability to be ready to implement the RO Model by January 1, 2020. CMS also seeks comments on delaying the start of the model performance period to April 1, 2020.

ACR Perspective and Comments

The ACR urges CMS to delay the beginning of the RO model performance period until July 1, 2020 and no sooner than April 1, 2020. Radiation oncology practices cannot be educated and prepared to participate in a new model when the final rule will not be released until early November, 2019 and the effective date is January 1, 2020. This allows less than 60 days for radiation oncology practices to be notified that they need to participate in the new model, become familiar with the process of reporting new episodes, measures, etc. These practices need at least six months for readiness in order for the model participants to have adequate time to prepare for the major changes this new model brings to the radiation oncology community.

Additionally, because CMS has not published specific data elements, vendors will be forced to develop and implement these changes in a short period of time. Many EHR and software upgrades take time to develop and make available to physician practices and hospitals. Also hospitals must plan ahead for budget approval for any upgrades and IT commitment to incorporate them into their systems. The typical timeframe for this type of planning is usually a year. **We therefore urge the Agency to delay implementation of this requirement until vendors have sufficient time to implement and upgrade current systems.**

Mandatory Model Design

Proposals

CMS believes that a mandatory model design would be the best way to improve the ability to detect and observe the impact of the prospective episode payments made under the RO Model. CMS therefore proposes that participation in the RO Model would be mandatory for all RT providers and RT suppliers furnishing RT services within the randomly selected CBSAs.

ACR Perspective and Comments

Although the ACR understands that the Centers for Medicare and Medicaid Innovation (CMMI) is planning on implementation of mandatory models in order to gain a reasonable level of participation, the RO model presented to CMS was designed to initiate voluntary participation with a gradual phase-in for risk, opt-in and opt-out, and other standard features. The ACR is surprised that CMS has proposed such an aggressive mandatory requirement given that this model is new and untested, with many model requirements that will be new and unfamiliar to radiation oncology practices. **The ACR requests that CMS allow for the RO model to be tested on a voluntary basis with a transition from no downside risk phasing into taking on more risk as data is collected on the performance of the model.** This is consistent with what CMS has allowed for the Comprehensive Joint Replacement Model and the Oncology Care Model.

The Agency should allow opt-in or opt-out for radiation oncology practices and health systems on behalf of all of their practices. This is similar to the approach that the Agency has taken with regard to ACOs, in which participants are tied to the ACO based on a shared TIN.

If the model is mandatory at the start or in the near future, **the ACR urges CMS to establish criteria by which small and/or rural practices that can demonstrate financial hardship can opt-out of the model.**

We feel that the Agency should allow an opportunity for practices to opt-into the model if they feel they want to participate and take advantage of its incentives as finalized in November.

RO Model Episodes

Included Services

Proposals

CMS proposes that the model would include most radiation therapy services, including consultation; treatment planning; dose calculation; radiation physics and dosimetry, treatment devices, and special services; treatment delivery; and treatment management. The Agency proposes to exclude evaluation and management (E/M) services from the model; however, radiation oncologists can continue to bill these codes under Medicare fee-for-service (FFS). Additionally, CMS is proposing to exclude low volume services from the model, including certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals.

ACR Perspective and Comments

The ACR agrees with CMS' definition of the distinct components in the delivery of radiation therapy and the events that would trigger an episode are reasonable. We are in agreement with the decision to exclude E/M services and the described low volume therapies from the model. We also agree with the exclusion of bundling

radiopharmaceuticals payments in the model, but urge CMS to insure that all related radiopharmaceuticals and radioelements remain excluded in the payment methodology. Examples are Y90 radioelement (HCPCS codes C2616/Q3001) and Radium-223 dichloride (HCPCS code A9606).

Proposals

CMS specifically invites public comments on the proposed inclusion of brachytherapy radioactive sources in the episodes. After considering either including or excluding brachytherapy radioelements from the RO Model, CMS is proposing to include brachytherapy radioactive elements, rather than omit these services, from the episodes because they are generally furnished in hospital outpatient departments (HOPDs) where the hospitals are usually the purchasers of the brachytherapy radioactive elements. When not furnished in HOPDs, these services are furnished in ASCs, which CMS is proposing to exclude from the Model.

ACR Perspective and Comments

Section 1833(t)(2)(H) of the Social Security Act requires that brachytherapy source payments be made separately from professional services in the hospital outpatient setting. Currently, brachytherapy sources are paid individual rates based on the type of radioactive source. Given the inherent differences in the types of sources needed for clinical care (including half-life, energy, dose rate, production in a medical reactor or cyclotron, and costs associated with manufacturing of the sources) the costs of each source can vary significantly and need to be ordered and made specifically for each patient. Billing for each patient would be based on the differences in isotopes, radioactive intensity, and the number of isotopes that are required for treatment of the individual patient.

The ACR recommends separate payment for brachytherapy sources in the RO model.

Included Modalities

Proposals

CMS proposes to include all modalities of treatment, including external beam therapy: three-dimensional conformal radiation therapy, intensity-modulated radiation therapy radiation therapy, stereotactic radiosurgery, stereotactic body radiation therapy radiation therapy, and proton beam therapy; intraoperative radiation therapy radiation therapy; image guided radiation therapy; and brachytherapy.

ACR Perspective and Comments

The ACR supports the inclusion of these modalities of treatment. However, the ACR wonders how CMS will consider the addition of new service lines and new technology that take place during the five-year period of the model.

New Service Lines and Equipment Replacement/Upgrades

Over the five-year term of the model, many practices are likely to add new service lines and upgrade existing equipment so they can continue to meet the clinical needs of cancer patients. The proposed RO Model payment methodology does not adequately address how CMS will recognize these important investments. **The ACR urges the Agency to consider establishing a rate review mechanism by which practices seeking to adopt new services lines or replace/upgrade existing equipment can submit an application for a rate review that would allow practices to make the argument for rate modifications during the term of the model.**

New Technology and Innovation

Radiation therapy has been utilized to deliver life-saving cancer treatments for well over 100 years. Advances in technology, particularly over the last quarter century, have allowed radiation oncologists to more precisely map the location of cancer, delivering higher, more effective doses of radiation that limit the exposure to normal tissue. To ensure the continued growth and adoption of new technology in the field of radiation oncology, **the ACR recommends that CMS pay FFS rates for any new technology identified by a new CPT code or new technology code during the term of the model.**

Cancer Types

Proposals

CMS is proposing to include 17 cancer types in the model, including Anal, Bladder, Bone Metastases, Brain Metastases, Breast, Cervical, CNS, Colorectal, Head and Neck, Kidney, Liver, Lung, Lymphoma, Pancreatic, Prostate, Upper GI, and Uterine. Additionally, the Agency states that it will notify RO Participants of any addition or removal of these proposed cancer types "per the CMS standard process for announcing coding changes and update the list on the RO Model website no later than 30 days prior to each performance year."

ACR Perspective and Comments

The ACR supports the inclusion of the 17 cancer types and the proposal to announce coding changes and updating the list for the model within 30 days prior to each performance year.

Multiple Disease Sites

Proposals

CMS proposes to pay one bundled rate regardless of whether the patient is seeking radiation treatment for one cancer type or concurrent treatments for multiple cancer types, including simultaneous treatments to primary disease sites and areas of symptomatic or oligometastatic disease.

ACR Perspective and Comments

The ACR believes that the occurrence of patients who are treated for multiple disease sites is more common than CMS realizes. For these cases, the cost of treatment can be significantly higher than those who are treated for a single disease site.

The ACR urges the Agency to continuously evaluate the frequency and cost-of-care associated with treatment of multiple disease site cases and consider a separate payment methodology for these more acute patient scenarios.

Episode Payment Construct

Proposals

CMS is proposing that each episode would have corresponding Professional Component (PC) and Technical Component (TC) payment amounts. These amounts represent the totals of calculated payment amounts for the professional and technical services of the radiation treatment furnished over the 90-day episode of care. The Agency proposes to calculate the payment amounts for the PC and the TC of each episode as the product of: 1) the OPPS or PFS national payment rates for each radiation therapy service included in the RO Model multiplied by 2) the volume of each professional and technical radiation therapy service included on a paid claim line during an episode of care.

ACR Perspective and Comments

The ACR supports CMS' proposed episode payment construct. It is consistent with the long-standing construct of the physician fee schedule and the original ACR/RVS as well as what is outlined in ASTRO's April 2017 concept paper.

Site Neutral Test and National Base Rate Development

Proposals

The RO Model proposal includes a "site neutral test" that would establish a common payment amount for services regardless of where they are furnished. The Agency believes this would offer RO participants more certainty regarding the pricing of radiation therapy services and remove incentives to promote the provision of radiation therapy services at one site over another. To establish this site neutral test, CMS is proposing to utilize historical HOPD episode payment data as the foundation for the development of National Base Rates for the PC and TC payment for each of the 17 disease sites. Episodes used to develop the national base rate include 1) episodes initiated between 2015-2017; 2) episodes attributed to a HOPD; and 3) during an episode, the majority of the technical services were provided in a HOPD. The Agency is proposing to use HOPD episodes, rather than freestanding and HOPD episodes, because it believes Outpatient Prospective Payment System (OPPS) payments have been more stable over time and have a stronger empirical foundation, because they are derived from hospital cost reports, than those under the Medicare Physician Fee Schedule (MPFS).

ACR Perspective and Comments

The ACR can support the concept of a site neutral test for the purpose of establishing rate stability. However, we are concerned with the Agency's decision to establish the site neutral test based on OPPS data alone. **The ACR strongly disagrees with CMS' assertion that OPPS data is more reliable and that payments have been more stable over time.** The ACR has conducted extensive studies over the years on how hospitals report their costs and charges. We find that the data is very mixed and unreliable. For example, in our comments on the CY 2020 HOPPS proposed rule, we have found that 85% of the hospitals reported costs are lower than the national average and their cost-to-charge ratios are much lower than the average .2.

In addition, the ACR, ASTRO and AAPM commented last year that the C-APC methodology under the hospital outpatient prospective payment system (HOPPS) does not account for the complexity of radiation oncology treatments, especially in the area of brachytherapy for the treatment of cervical cancer. The standard of care for a cervical cancer patient includes external beam radiation therapy/5 brachytherapy insertions/chemotherapy all completed within 56 days of treatment start. We presented to CMS last year that the charge capture under the CMS methodology falls short of capturing all of the costs for a cervical cancer patient and thus severely under-pays the hospital for its costs to provide these services. The 2018 Medicare HOPPS payment for cervical brachytherapy treatment is $2,272.61, which is:

$13,731.51 less than the average cost for the brachytherapy portion of the treatment; and
$40,000 less than the average cost for brachytherapy and external beam radiation therapy (partial treatment).

The ACR believes that a more accurate National Base Rate can be achieved through a blend recognizing MPFS and HOPPS rates, for both the professional and technical component. RO model participants need to be paid adequately to cover their costs in order for them to be able to remain as participants in this five-year model.

Discounts and Withholds

Proposals

The Agency proposes a Discount Factor of 4 percent for the PC and 5 percent for the TC. CMS believes that the proposed Discount Factors strike a balance between creating savings for Medicare, while not creating substantial financial burden on radiation oncology participants.

CMS also proposes an incorrect payment withhold, and either a quality withhold, or a patient experience withhold, depending on the type of component (PC or TC) furnished during the episode. The 2 percent incorrect payment withhold reserves money for purposes of reconciling duplicate radiation therapy services and incomplete episodes during the reconciliation process.

The 2 percent quality withhold for the professional component allows the model to include quality measure results as a factor in determining payment to model participants. Professional

and dual participants would be able to earn back up to the 2 percent withhold amount each year based on their aggregate quality score (AQS). A separate 1 percent patient experience withhold would be applied, starting in 2022, to the technical component to account for patient experience in the model through the implementation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey for Radiation Therapy.

ACR Perspective and Comments

The discount factors represent a significant and excessive cut. Additionally, combined with the withholds, they have the potential to put many practices at financial risk, particularly those with thin operating margins. **The ACR recommends that the Agency reduce the discount factors to 3 percent for both the PC and the TC payment. Additionally, we urge CMS to forward fund the withholds, so that revenues are not tied up during the 20-month post performance period reconciliation and true up process.**

Recognition of 2020 and 2021 MIPS Performance Bonus Payments

Proposals

CMS proposes to omit Merit Based Incentive Payment System (MIPS) bonus payments from the historical payment methodology for practices who have successfully complied with MIPS reporting requirements in payment years 2020 and 2021, based on performance years 2018 and 2019.

ACR Perspective and Comments

The ACR strongly believes that CMS should honor its commitment to MIPS practices that have operated in good faith and complied with program requirements by issuing the MIPS bonus payments in the payment methodology for 2020 and 2021.

Quality Measures

Proposals

CMS proposes to adopt the following set of quality measures for the RO Model to assess the quality of care provided during episodes. The Agency believes these measures allow it to quantify the impact of the Model on quality of care, radiation therapy services and processes, outcomes patient satisfaction, and organizational structures and systems.

Quality Measure	Level of Reporting	Pay for Reporting	Pay for Performance
Oncology: Medical and Radiation – Plan of Care for Pain (NQF41 #0383; CMS Quality ID #144)	Aggregate	N/A	PYs 1-5
Preventative Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality Data ID #134)	Aggregate	N/A	PYs 1-5
Advanced Care Plan (NQF #0326; CMS Quality ID #047)	Aggregate	N/A	PYs 1-5
Treatment Summary Communication – Radiation Oncology	Aggregate	PYs 1-2	PYs 3-5
CAHPS Cancer Survey for RT	Patient-Reported	N/A	PYs 3-5
Clinical Data Elements	Beneficiary-Level	PYs 1-5	TBD

ACR Perspective and Comments

The proposed rule does not specify which benchmarks and collection types the Agency is using for these measures. **The ACR recommends that MIPS benchmarks and collection types be used to ease transition into the RO APM and align quality reporting programs. Without information on how data will be submitted to CMS for this model, we urge CMS to consider allowing practices to use relevant third parties for data collection and reporting, as it does in other quality reporting programs.**

The ACR notes that NQF measures #0418 and #0326 are considered topped out, which means that participants would not receive the full 10 points, thus putting them at a disadvantage in the overall scoring. **The ACR requests that given the small amount of measures applicable to this model, including no outcome measure, that CMS give full credit and as much flexibility as possible to allow practices to earn as many points as possible for their efforts and thus earn back their quality withholds.**

Proposed Clinical Data Collection

Proposals

In addition to collecting quality measure data, CMS is also proposing to collect clinical information on certain Medicare beneficiaries from Professional and Dual participants. On a pay-for-reporting basis, the Agency is proposing that both Professional and Dual participants report basic clinical information, not available on claims or captured in quality measures, on Medicare

FFS beneficiaries treated for prostate, breast, lung, bone metastases, and brain metastases. CMS proposes to use the data to support clinical monitoring and evaluation of the RO Model. CMS also proposes that participants must report 95% of their Medicare patients meeting the denominator specifications (i.e., being treated for the five categories). The Agency will determine specific data elements and reporting standards prior to the start of the Model.

ACR Perspective and Comments

The ACR believes that setting a reporting requirement at 95% is very burdensome. Many practices struggle under MIPS to report at 70% and would find any requirement above this to be unattainable. **The ACR recommends that CMS begin with a 70% reporting requirement and reassess whether that level can be increased in future years.**

Monitoring for Compliance

Proposals

In order to monitor for compliance, the Agency is also proposing that all Professional participants and Dual participants document in the medical record that they have complied with seven monitoring requirements. This includes discussing goals of care with the beneficiary, adherence to nationally recognized, evidence-based treatment guidelines, assessing the beneficiaries' cancer stage for diagnosis, assessing beneficiaries performance status as a quantitative measure, sending a treatment summary to the referring physicians, discuss cost-sharing with the beneficiary and performing and documenting peer review.

ACR Perspective and Comments

The ACR has extensive experience and resources available to radiation oncologists and hospitals by way of accreditation, peer review, practice guidelines and parameters, registries and clinical decision support. **The ACR recommends that CMS does not require development of separate programs for monitoring compliance but instead utilize what ACR and other specialty societies have already developed to ensure practice adherence to quality and compliance.**

Local Coverage Determinations

Proposals

CMS asserts that the local coverage determinations (LCDs), would still apply to all radiation therapy services provided in an episode.

ACR Perspective and Comments

Given the uniqueness of the RO model, the ACR believes that having radiation oncology practices follow the requirements of the RO model and then also those of their local coverage determinations is overly burdensome. Isn't the implementation of the RO model considered national policy of which then overrides LCDs? **The ACR believes that CMS should waive the**

need for model participants to have to adhere to LCDs. This may also reduce burden for CMS' Medicare Administrative Contractors.

RO Model: Advanced APM and MIPS APM

Proposals

CMS intends for the RO Model to qualify as an Advanced APM and to also meet the criteria to be a MIPS APM. The Agency proposes that the RO participant, specifically either a Professional participant or a Dual participant, would be the APM entity. The Agency projects that 82 percent of RO participants will receive the APM incentive payment for at least one performance period during the model performance period, based on applying the 2019 Quality Payment Program (QPP) final rule qualification criteria to simulated billing and treatment patterns for each QPP performance year during the RO model test.

In order to be an Advanced APM, an alternative payment model must satisfy three specific criteria 1) Use of Certified Electronic Health Records Technology; 2) Payment Based on MIPS comparable quality measures; and 3) Meet the nominal financial risk standard. Additionally, MACRA sets forth that full capitation arrangements also meet the criteria for Advanced APMs.

CMS is proposing to waive the MACRA-required Technical Component Payments in the calculation of the APM incentive payment. According to MACRA, Qualified Advanced APM Participants are eligible to receive 5 percent of his or her prior year estimated aggregate payments for covered professional services. CMS believes it is necessary to exclude payments for the technical RO Model-specific HCPCS codes from the estimated aggregate payment amounts for covered professional services used to calculate the APM incentive payment because those services are considered "technical" in nature and represent the cost of the equipment, supplies and personnel used to perform the procedure.

CMS asserts that if the waiver were not applied and technical RO Model-specific HCPCS codes are included in the calculation, then radiation oncologists delivering radiation therapy services in the freestanding setting would have technical radiation therapy services included in the calculation of the APM incentive payment, but radiation oncologists delivering radiation therapy services in hospital outpatient settings would not have those services included in the calculation of the APM incentive payment. CMS believes this scenario would result in Dual participants changing their billing behavior by shifting their site of service from the hospital setting to the freestanding setting, thus jeopardizing the site neutral intent of the model.

ACR Perspective and Comments

Given that CMS proposed to use a site neutral payment, there is no reason for participants to change their billing behavior or shift their site of service from one setting to another. The statute establishes a payment to incentivize participation in Advanced APMs and CMS has interpreted that payment to be contingent on participation alone. CMS proposes to mandate participation *and* to waive its obligation to pay for such participation. When put together, these arbitrary actions bring radiation therapy providers into a new payment model that fails to compensate

them for their participation. This regulatory action conflicts with the spirit and letter of MACRA and suggests that the incentive waiver is nothing more than a payment cut disguised as a test. **The ACR recommends removing the waiver for the APM incentive payment and allowing for the 5% bonus payment to be applied to the technical payments of freestanding centers.**

Conclusion

The ACR appreciates the opportunity to comment on the proposed RO Model. We appreciate CMS including us in this comment and evaluation process. In addition to the submission of these formal comments, **the ACR fully supports the more detailed comments as submitted by the American Society for Radiation Oncology (ASTRO)**. If you have any questions or comments on our letter, please do not hesitate to contact Pam Kassing at (800) 227-5463 x4544 or via email at pkassing@acr.org.

Respectfully Submitted,

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