

September 13, 2021

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Radiation Oncology Model; Proposed Rule; CMS-1753-P

Dear Administrator Brooks-LaSure:

The American Association of Physicists in Medicine¹ (AAPM) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 4, 2021 *Federal Register* notice regarding the 2022 Medicare Hospital Outpatient Prospective Payment System (HOPPS), Ambulatory Surgical Center (ASC) Payment System and Radiation Oncology (RO) Model proposed rule.

The AAPM provides the following recommendations:

- Reassign CPT code 76145 *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report from APC 5611 Level 1 Therapeutic Radiation Treatment Preparation* to APC 5724 *Level 4 Diagnostic Tests and Related Services*. Alternatively, reassign CPT 76145 to New Technology APC 1510 beginning January 1, 2022.
- Discontinue the Comprehensive APC payment policy for all brachytherapy insertion codes. Alternatively, modify the C-APC methodology to pay for “J1” brachytherapy insertion device and make separate payment for related planning and preparation services in addition to the C-APC payment effective January 1, 2022.
- Support the proposal for the Low Volume APC policy effective January 1, 2022.
- Reduce the Radiation Oncology Model discount factors to 3 percent for both the Professional Component (PC) and the Technical Component (TC) payment.

¹ The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MRI, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

- If CMS finalizes the proposal to remove brachytherapy services from the Radiation Oncology Model, it should also remove the waiver of section 1833(t)(2)(H) of the Act.
- Support voluntary compliance of Radiation Oncology Model monitoring requirements until CMS provides additional guidance regarding how the Agency expects practices to collect and report on this data, electronic health record (EHR) vendors have had time to develop the necessary software for the collection of additional data and RO Model Participants have been able to upgrade their systems.
- Remove the Radiation Oncology Model waiver for MACRA-required Technical Component Payments in the calculation of the APM incentive payment and allow for the 5 percent bonus payment to be applied to the technical payments of freestanding radiation therapy centers.
- Oppose the inclusion of any new physician group practices (PGPs) or hospital outpatient departments (HOPDs), including Pennsylvania Rural Health Model (PARHM) eligible groups, in the Radiation Oncology Model.
- Support the proposed Radiation Oncology Model Extreme and Uncontrollable Circumstances policy.

1. **Reassignment of CPT 76145**

CPT 76145 is a new medical physics code that was implemented on January 1, 2021.

- 76145 Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report

CPT 76145 is used to describe the medical physicist's work in performing a patient-specific peak organ dose calculation subsequent to an interventional radiology or interventional cardiology procedure exceeding the facility's established threshold for radiation air kerma from one or more procedures.

Typically, the medical physicist will review the request and verify that the institutional review threshold has been exceeded. In addition, the medical physicist will ascertain if adverse skin or other organ injuries have been reported, consistent with typical time-dose response effects. The medical physicist reviews the procedure with the physician and imaging staff.

The work includes a patient specific calculation and tabulation of the input calculation data for each imaging segment [and sub-segments if there is a significant change in x-ray parameter(s)], resultant organ dose for each segment and total peak organ dose for all segments for the maximally exposed tissue. Further, there is a review of the anticipated tissue response based on time/dose/effect literature. The medical physicist will verify the recorded reference air kerma, entrance skin air kerma, and other relevant radiation parameters input to the calculation by independent radiation exposure measurements in the procedural room using the same equipment and techniques as were used for the clinical procedure.

CMS proposes to maintain assignment of the medical physics code 76145 to APC 5611 *Level 1 Therapeutic Radiation Treatment Preparation* with a 2022 proposed payment of \$130.19. APC 5611 has nine, clinically similar, radiation oncology therapeutic radiation treatment codes. CPT 76145 is not a radiation oncology code used in the treatment of cancer patients. CPT 76145 describes a patient-specific peak organ dose calculation that can be utilized across a broad spectrum of radiology or cardiology services. The dose evaluation service is not provided as part of treatment preparation but after an interventional radiology or interventional cardiology service(s).

AAPM recommends that CPT 76145 be reassigned to APC 5724 *Level 4 Diagnostic Tests and Related Services*. APC 5724 currently has 17 services, with a range of clinical variability (urology, neurology, internal medicine, radiology, dermatology, allergy, etc.). The proposed 2022 payment for APC 5724 is \$943.96. The resource consumption in APC 5724 more closely aligns with the resources used to perform CPT 76145.

Alternatively, CMS could reassign CPT 76145 to New Technology APC 1510, which more closely aligns reimbursement to the current 2021 Medicare Physician Fee Schedule payment rate of \$848.25. Assignment to New Technology APC 1510 effective January 1, 2022 would allow the Agency time to collect and analyze outpatient claims data for more appropriate assignment to a clinical APC in the future.

The AAPM recommends that CMS reassign CPT code 76145 *Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report from APC 5611 Level 1 Therapeutic Radiation Treatment Preparation* to APC 5724 *Level 4 Diagnostic Tests and Related Services* effective January 1, 2022. Alternatively, CMS could reassign CPT 76145 to New Technology APC 1510 beginning January 1, 2022.

2. Comprehensive APC Methodologies for Surgical Insertion Codes for Brachytherapy

CMS continues to utilize 69 Comprehensive Ambulatory Payment Classifications (C-APC) in CY 2022. Under the C-APC policy, CMS provides a single payment for all services on the claim regardless of the span of the date(s) of service. Conceptually, the C-APC is designed so there is a single primary service on the claim, identified by the status indicator (SI) of “J1”. All adjunctive services provided to support the delivery of the primary service are included on the claim.

Since the inception of the Comprehensive APC methodology, the AAPM has commented on concerns around the claims data used for ratesetting due to significant variations in clinical practice and billing patterns across the hospitals that submit these claims. We met with CMS staff in February 2018 and in our 2019 & 2020 HOPPS proposed rule comment letters, the AAPM proposed a modified C-APC methodology for the surgical codes related to brachytherapy that mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes. For CY 2022, CMS proposes to continue the flawed C-APC payment methodology for the surgical insertion codes for brachytherapy treatment. To date, the Agency has not addressed these concerns and the impact on Medicare beneficiary access to brachytherapy in the hospital outpatient setting is evident.

While AAPM supports policies that promote efficiency and the provision of high-quality care, we have long expressed concern that the C-APC methodology lacks the appropriate charge capture mechanisms to accurately reflect the services associated with the C-APC.

The AAPM remains concerned that the rates associated with C-APCs do not accurately or fully reflect the services and costs associated with the primary procedure. The current C-APC methodology is of particular concern as CMS continues to expand the number of packaged and bundled services. Given the complexity of coding, serial billing for cancer care, and potentially different sites of service for the initial surgical device insertion and subsequent treatment delivery or other supportive services, the AAPM continues to oppose the current comprehensive APC payment methodology for cancer care. **We urge the Agency to explore alternatives to the C-APC methodology so that it appropriately values this life saving service.**

The current Comprehensive APC payment methodology for brachytherapy does not accurately reflect the true cost of providing the procedures.

The AAPM recommends that CMS discontinue the Comprehensive APC payment policy in 2022 for all brachytherapy insertion codes. CMS should revert to status indicator “T” for CPT codes 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55875, 55920, 57155 and 58346.

Alternatively, CMS could continue to pay for “J1” brachytherapy insertion codes under the C-APC payment methodology but exclude and make separate payment for designated preparation and planning services in addition to the C-APC payment (see Attachment A).

3. Low Volume APC Policy

CMS proposes to designate clinical APCs, brachytherapy APCs, and New Technology APCs with fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year (the CY 2019 claims year for this CY 2022 proposed rule) as Low Volume APCs. **We agree with CMS that low utilization of services can lead to wide variation in payment rates from year to year, especially as it relates to brachytherapy sources.** Under the proposed Low Volume APC policy, the payment rates for these APCs would be set at the highest amount among the geometric mean, median, or arithmetic mean, calculated using up to four years of data.

The AAPM supports the proposed Low Volume APC policy effective January 1, 2022.

4. Radiation Oncology Model

CMS proposes the creation and testing of a new alternative payment model for radiation oncology (RO Model) that tests whether prospective, site-neutral, modality agnostic, episode-based payments to physician group practices (PGPs), hospital outpatient departments (HOPDs) and freestanding radiation therapy centers would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

While we support CMS efforts to establish an alternative payment methodology for radiation oncology that would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries, **we have grave concerns regarding the payment and pricing methodology, undue administrative and financial burden, and the potential negative impact on Medicare beneficiary access to safe and high-quality cancer care. Severe consequences include limiting access to care by closure of radiation oncology facilities or reduction of services, which, in particular will especially impact underserved populations and initiatives seeking to address healthcare disparities.**

Reducing payment will not improve quality but jeopardize access to safe and effective radiation treatments by putting too much financial strain on radiation oncology practices that have no choice but to participate. With virtually no positive incentives, payment cuts of this magnitude to required RO participants are unjustified. The currently proposed RO Model does not meet the intent of the MACRA legislation nor move toward value-based payments.

The proposed RO Model is complicated and requires changes to coding, claims generation, claims processing, participant-specific modifiers and adjustments, withhold calculations, payment programming, and software updates for electronic health records (EHRs). Operationalizing the RO Model on both the Medicare contractor side and mandatory RO participant side will be extremely challenging.

The AAPM supports a radiation oncology alternative payment model that provides fair and predictable payment to protect Medicare beneficiary access to cancer care, and incentivizes the appropriate use of cancer treatments that result in the highest quality of care and best patient outcomes.

Discount Factors:

CMS proposes a discount factor of 3.5 percent for the Professional Component (PC) and 4.5 percent for the Technical Component (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 withholds PC and TC payments for incomplete episodes (2%), PC quality withhold (2%) and TC patient satisfaction withhold (1% beginning in performance year 3)

The discount factors represent a significant and excessive payment reduction, which risks patient access by causing significant financial issues for such a capital expenditure intensive specialty. Additionally, combined with the withholds, reduced payments have the potential to put many practices at financial risk.

The AAPM recommends that CMS reduce the Radiation Oncology Model discount factors to 3 percent for both the Professional Component (PC) and Technical Component (TC) payment.

Reducing the discount factors to 3 percent would still generate Medicare savings.

Exclusion of Brachytherapy Services:

CMS proposes to omit brachytherapy, one of the most cost-effective, high-value modalities of treatment from the RO Model. The AAPM had previously recommended that CMS provide an alternative payment methodology for multi-modality RT services (i.e., combination therapy) provided during a 90-day episode of care. Given the RO Model's limitations and inability to account for the added expense of brachytherapy when combined with external beam radiation therapy (EBRT), it is reasonable to exclude brachytherapy from the RO Model. However, this does not address the overarching concerns regarding the inadequate reimbursement for brachytherapy services that have created access to care issues for this particular modality for years.

If CMS finalizes the proposal to remove brachytherapy services from the Radiation Oncology Model, it should also remove the waiver of section 1833(t)(2)(H) of the Act.

Monitoring Requirements:

RO participants would be required to submit encounter data (i.e., no-pay) claims that include all RT services identified on the RO Model Bundled HCPCS list as services are furnished and would otherwise be billed under the Medicare FFS systems. These claims will not be paid because the bundled payments cover RT services provided during the episode. **We have concerns regarding administrative burdens with provider requirements to track all RT services as they are furnished.**

In addition, CMS would require Professional Participants and Dual Participants to report basic clinical information not available in claims or captured in quality measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) prostate, (2) breast, (3) lung, (4) bone metastases, and (5) brain metastases.

There is no reimbursement associated with the additional monitoring requirements, only excessive payment cuts when participants fail to comply with these requirements. **We have concerns regarding administrative and financial burden associated with additional pay-for-reporting requirements.** In addition, electronic health records (EHRs) don't currently collect this data and EHR vendors will need time to develop the software to collect additional data elements.

The AAPM recommends voluntary compliance of Radiation Oncology Model monitoring requirements until CMS provides additional guidance regarding how the Agency expects practices to collect and report on this data, EHR vendors have had time to develop the necessary software for the collection of additional data and Radiation Oncology Model Participants have been able to upgrade their systems.

Waiver of 5 Percent Bonus on Technical Services:

CMS plans 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 services. We believe that the waiver is arbitrary and a violation of MACRA. The waiver further limits community-based clinics from investing in the technology necessary to provide high quality cancer care.

The AAPM recommends that CMS remove the waiver for MACRA-required Technical Component Payments in the calculation of the APM incentive payment and allow for the 5 percent bonus payment to be applied to the technical payments of freestanding radiation therapy centers.

Participant Exclusions:

CMS proposes to modify the Pennsylvania Rural Health Model (PARHM) exclusion by only excluding those practices that are participating in PARHM, rather than those that are eligible to participate but choose not to participate. CMS justifies this by stating that those participating in PARHM receive global budgets that include payment for RT services and would therefore overlap with the RO Model payment. Those that are eligible but not participating in PARHM are not subject to this potential overlap in payment; therefore, CMS is proposing that they be mandated to participate in the RO Model.

The AAPM opposes the inclusion of any new physician group practices (PGPs) or hospital outpatient departments (HOPDs), including Pennsylvania Rural Health Model (PARHM) eligible groups, in the RO Model.

We remain concerned that the model is untested and presents a significant financial and administrative burden on those selected to participate. For these reasons, we do not believe it is appropriate to include PARHM eligible practices in the RO Model.

Extreme and Uncontrollable Circumstances:

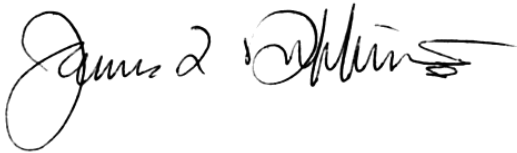
CMS proposes to adopt an Extreme and Uncontrollable Circumstances (EUC) policy for the RO Model. CMS proposes to define an EUC as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale. CMS proposes that if CMS declares an EUC for a geographic region, CMS may: (1) amend the model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. Application of the modifications would be based on the severity and types challenges that the circumstance imposes on RO participants. CMS would seek to minimize impact on the RO participants not affected by the EUC, while supporting those that are affected.

The AAPM supports the proposed Radiation Oncology Model Extreme and Uncontrollable Circumstances policy.

We hope that CMS will consider these issues during the development of the 2022 Medicare HOPPS and Radiation Oncology Model final rule.

Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2503.

Sincerely,

A handwritten signature in black ink that reads "James T. Dobbins III". The signature is written in a cursive style with a prominent loop at the beginning and a long, sweeping tail.

James T. Dobbins III, PhD, FAAPM
President, American Association of Physicists in Medicine
Strategic Advisor to the Provost and Former Associate Vice Provost
Professor of Radiology, Biomedical Engineering, and Physics, and Faculty in Medical Physics
Duke University

A handwritten signature in black ink that reads "Michele S. Ferenci". The signature is written in a cursive style with a large, open loop at the beginning and a long, sweeping tail.

Michele S. Ferenci, Ph.D.
Chair, Professional Economics Committee

ATTACHMENT A

The AAPM identified a list of twenty-eight (28) codes proposed for separate payment in addition to the C-APC payment for the brachytherapy insertion codes (CPT 19296, 19298, 19499, 20555, 31643, 41019, 43241, 55875, 55920, 57155, 58346) effective January 1, 2022 (see below). Not all planning and preparation codes would be utilized for each brachytherapy insertion procedure code listed 3 above. This C-APC modified policy mirrors the current CMS payment policy for single-session cranial stereotactic radiosurgery codes 77371 and 77372, which allows separate payment for specified preparation and planning codes.

- 10035 Placement of soft tissue localization device (egg, clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including image guidance; first lesion
- 32553 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple
- 49411 Placement of interstitial devices for radiation therapy guidance (egg fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvis (except prostate), and/or retroperitoneum, single or multiple
- 55874 Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance
- 55876 Placement of interstitial device(s) for radiation therapy guidance, prostate, single or multiple
- 76000 Fluoroscopy, up to 1 hour physician or other qualified health care professional time
- 76872 Ultrasound, transrectal
- 76873 Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning
- 77280 Therapeutic radiology simulation-aided field setting; simple
- 77285 Therapeutic radiology simulation-aided field setting; intermediate
- 77290 Therapeutic radiology simulation-aided field setting; complex
- 77295 3-dimensional radiotherapy plan, including dose-volume histograms
- 77300 Basic radiation dosimetry calculation
- 77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
- 77306 Teletherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77307 Teletherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77316 Brachytherapy isodose plan; simple, include basic dosimetry calculation(s)
- 77317 Brachytherapy isodose plan; intermediate, include basic dosimetry calculation(s)
- 77318 Brachytherapy isodose plan; complex, include basic dosimetry calculation(s)
- 77321 Special teletherapy port plan
- 77331 Special dosimetry, only when prescribed by treating physician
- 77332 Treatment devices; simple
- 77333 Treatment devices; intermediate
- 77334 Treatment devices; complex
- 77336 Continuing medical physics consultation
- 77338 Multi-leaf collimator devices for IMRT
- 77370 Special medical radiation physics consultation
- C9728 Placement of interstitial devices for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach); abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple