

September 10, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies under the Medicare Physician Fee Schedule for CY 2019; Proposed Rule; CMS-1693-P

Dear Administrator Verma.

The American Association of Physicists in Medicine (AAPM)¹ is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 27, 2018 *Federal Register* notice regarding the 2019 Medicare Physician Fee Schedule (MPFS) proposed rule.

The AAPM provides the following recommendations.

- AAPM recommends that CMS utilize the existing practice expense inputs for equipment items ER003, ER083 and ES052. AAPM believes the current prices for those items, which were established through the RUC process, should be retained.
- AAPM supports the 4-year phase-in of updated medical equipment and supply pricing from 2019-2022. We urge CMS to allow invoice submission during the entire 4-year period to ensure that direct practice expense inputs reflect up-to-date and accurate pricing.
- AAPM recommends that CMS evaluate clinical labor rates after the 4-year pricing transition for medical equipment and supplies is complete.
- AAPM opposes the proposed technical modification to the practice expense methodology for evaluation and management services due to the unintended consequences of decreased practice expense RVUs for multiple radiation oncology services.
- AAPM supports the RUC-recommended and CMS approved relative value units (RVUs) for Fluoroscopy code 76000.

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, MR, 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.

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- AAPM continues to emphasize that any codes utilized as part of superficial radiation treatment delivery that include medical physics time should require that a qualified medical physicist perform the physics work.
- AAPM recommends that CMS revise its proposal to reflect language used in the preamble to allow AUC consultations by clinical staff and <u>not</u> auxiliary personnel.
- AAPM supports the CMS proposal to require a direct level of physician supervision for diagnostic tests performed by a Radiologist Assistant, in accordance with state laws.

I. Updates to Prices for Existing Direct Practice Inputs

CMS initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the MPFS direct practice expense (PE) inputs for supply and equipment pricing for CY 2019. StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicate that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. After reviewing the StrategyGen report, CMS is proposing to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

While the AAPM supports CMS efforts to update equipment and supply pricing to reflect current costs, the AAPM also believes that the proposed post-transition pricing for certain medical equipment items used for cancer care are inaccurate. The lack of transparency of the contractor process and specific inputs (i.e. manufacturer name, model and price) used to develop updated pricing are concerning. In particular, the AAPM believes the three (3) medical equipment items shown in Table 1 are significantly undervalued relative to fair market pricing.

Table 1

Equipment Item	2018 Current Price	2022 Recommended Price	Percentage Change Over 4-Year Transition Period
ER003 HDR Afterload System, Nucletron - Oldelft	\$375,000	\$111,426	-70%
ER083 SRS System, SBRT, Six Systems	\$4,000,000	\$931,965	-77%
ES052 Brachytherapy Treatment Vault	\$175,000	\$134,998	-21%

By way of example, SRS LINAC (ER082) and SBRT LINAC (ER083) systems are similar in both technological complexity and pricing in the current marketplace, yet the proposed StrategyGen pricing would value the latter (\$931,965) at a small fraction of the former (\$4,195,100). All equipment items shown in Table 1 have recommended prices that are below industry standards. Given the high cost of these items and their substantial utilization in certain radiation oncology delivery codes, it is imperative that CMS inputs accurately reflect the marketplace pricing.

The 2018 price for the Nucletron Oldelft High Dose Rate (HDR) Afterload System (ER003) is \$375,000. CMS proposes a new price of \$111,426, a 70 percent pricing reduction. We think that StrategyGen may have included updated pricing for a less costly <u>electronic</u> brachytherapy system used to treat non-melanoma skin cancer. This equipment type would not be utilized with procedures that utilize a HDR afterloader (i.e. CPT 77767, 77768, 77770, 77771 and 77772). Alternatively, the new recommended price may represent an equipment upgrade or refurbished equipment. Due to the lack of transparency, we are not able to verify the specific types of medical equipment used to determine the new pricing for ER003, but it is clearly in error.

The 2018 price for the Brachytherapy Treatment Vault (ES052) is \$175,000. CMS proposes a new price of \$134,998. Invoices for the Brachytherapy Treatment Vault were submitted in 2015 when the HDR Brachytherapy codes were last revalued by the AMA Relative Value Scale Update Committee (RUC). The recent pricing data supports the current price of \$175,000.

AAPM recommends that CMS utilize the existing practice expense inputs for equipment items ER003, ER083 and ES052. AAPM believes the current prices for those items, which were established through the RUC process, should be retained.

In addition, CMS is proposing to phase-in the use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. We agree that implementing the proposed updated prices with a 4-year transition will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items.

AAPM supports the 4-year phase-in of updated medical equipment and supply pricing from 2019-2022. We urge CMS to allow invoice submission during the entire 4-year period to ensure that direct practice expense inputs reflect up-to-date and accurate pricing.

To maintain relativity between the clinical labor, supplies, and equipment portions of the practice expense methodology, CMS believes that the rates for the clinical labor staff should also be updated along with the updated pricing for supplies and equipment. CMS seeks public comment regarding whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the 4-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition for supplies and equipment.

AAPM recommends that CMS evaluate clinical labor rates after the 4-year pricing transition for medical equipment and supplies is complete.

II. Evaluation and Management Codes

CMS is proposing a number of coding and payment changes to reduce administrative burden and improve payment accuracy for evaluation and management (E/M) visits, including a technical modification to the practice expense methodology.

As CMS notes in the 2019 proposed rule, E/M visits comprise a significant portion of allowable charges under the MPFS and are used broadly across specialties such that the proposed changes can greatly impact the change in payment at the specialty level and at the practitioner level. CMS proposes to simplify payment for E/M visit levels 2 through 5, and to take into consideration that there are inherent differences in primary care-focused E/M services and in more complex E/M services such that those visits involve greater relative resources, while seeking to maintain overall payment stability across specialties.

Specifically, CMS is proposing to create a single PE/HR value for E/M visits (including all of the proposed HCPCS G-codes) of approximately \$136, based on an average of the PE/HR across all specialties that bill these E/M codes, weighted by the volume of those specialties' allowed E/M services. Establishing a single MPFS rate for new and established patient E/M levels 2 through-5 would have a large and unintended effect on many specialties due to the way that indirect PE is allocated based on the mixture of specialties that furnish a service. This proposal significantly impacts the Indirect Practice Expense Cost Indices (IPCI) portion of the practice expense component, which inappropriately impacts the relativity of the MPFS.

AAPM applauds the Agency for its sweeping proposals to reduce administrative burden for healthcare professionals. The unintended consequence of modifying the practice expense methodology to create a single PE/HR for E/M visits negatively impacts radiation oncology practice expense, which is not justified by the new E/M documentation and payment policies.

AAPM opposes the proposed technical modification to the practice expense methodology for evaluation and management services due to the unintended consequences of decreased practice expense RVUs for multiple radiation oncology services.

III. 2019 Proposed Relative Value Units (RVUs)

A. Fluoroscopy (76000)

CMS is proposing the RUC-recommended work RVU of 0.30 for CPT code 76000 (Fluoroscopy (separate procedure), up to 1 hour physician or other qualified health care professional time, other than 71023 or 71034 (e.g., cardiac fluoroscopy)).

AAPM supports the RUC-recommended and CMS approved work relative value units (RVUs)of 0.30 for CPT 76000.

B. Superficial Radiation Treatment (77401)

In the 2015 MPFS, CMS finalized language limiting the codes that could be reported with superficial radiation treatment (SRT). At that time, the CPT Panel considered and ruled out potential reporting of other radiation therapy services with CPT code 77401, but did determine that a physician evaluation and management code may be reported, when performed, if CPT 77401 is billed alone.

In the 2018 CMS proposed to make separate payment for the professional planning and management associated with superficial radiation treatment using HCPCS code GRRR1. CMS did <u>not</u> propose to include inputs related to radiation physics consultation, described by CPT 77336, as they think that a typical course of SRT would not require this service, and the typical practitioner providing SRT would not be performing a physics consultation. In the 2018 MPFS final rule, CMS did not finalize the proposal to implement HCPCS code GRRR1.

Given stakeholder feedback following the publication of the 2018 MPFS final rule, CMS continues to believe that there are potential coding gaps for SRT-related professional services. CMS generally relies on the CPT process to determine coding specificity, and believes that deferring to this process in addressing potential coding gaps is generally preferable.

CMS is not proposing changes related to SRT coding, SRT-related professional codes, or payment policies for 2019. However, CMS is seeking comment on the possibility of creating multiple G-codes specific to services associated with SRT. Specifically, CMS states that "these codes would be used separately to report services including SRT planning, initial patient simulation visit, treatment device design and construction associated with SRT, SRT management, and medical physics consultation."

The AAPM recommends that newly proposed services be subject to the AMA Current Procedural Terminology (CPT) Editorial Panel and Relative Value Scale Update Committee (RUC) processes. If CMS chooses to develop separate HCPCS G codes to describe services associated with SRT, we support three G-codes to describe treatment planning, devices and management based on crosswalks to existing CPT codes 77261, 77332 and 99213, respectively. The proposed G codes should specify a maximum frequency for each course of treatment: GRRR1 SRT Treatment Planning – once per course of treatment; GRRR2 SRT Treatment Device – once per field per course of treatment if devices are created; and GRRR3 SRT Treatment Management – once per week. In addition, we understand that there is a significant increase in the billing of simulation and dosimetry with SRT. We recommend that, when performed, a single instance of CPT code 77300 per field, and a single instance of 77280 per course of treatment should be specified.

The AAPM is concerned that CMS does not explicitly make clear the role of the Qualified Medical Physicist (QMP) in the delivery of superficial radiation treatment delivery. It is crucial that any course of treatment involving external beam radiation therapy be subject to a quality management process provided by a QMP to improve efficacy and safety. The QMP services typically include, but may not be limited to: calibration and performance testing of the equipment, technical consultation at simulation as to optimal patient positioning; choice of treatment beam energy and appropriate applicators; confirmation that the treatment plan and dosimetry calculation are performed accurately and in accordance with the written prescription; supervision of technical details of the treatment delivery; and timely review of the patient records at the presumed end of treatment to assure that the entire prescription has been accurately fulfilled in its entirety and appropriately documented. These services are generally captured and billed in radiation therapy using CPT 77336 Continuing medical physics consultation.

AAPM continues to emphasize that any codes utilized as part of superficial radiation treatment delivery that include medical physics time should require that a qualified medical physicist perform the physics work.

IV. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

The Protecting Access to Medicare Act of 2014 establishes a program to promote the use of Appropriate Use Criteria (AUC) for advanced diagnostic imaging services. CMS is proposing to allow AUC consultations, when not personally performed by the ordering professional, to be performed by auxiliary personnel. CMS states that this will allow the ordering professional to exercise their discretion to delegate the performance of this consultation.

The AAPM understands that CMS needs to address concerns from some stakeholders about the potential burden of the AUC program. The statute is clear that the ordering professional is required to consult the AUC, which we believe requires the ordering professional to meaningfully interact with the clinical decision support mechanism program. CMS should not lose sight of Congress's intent to educate ordering professionals in the optimal use of advanced diagnostic imaging services. This education cannot take place if the ordering professionals have no contact with the AUC themselves.

The AAPM supports flexibility for ordering professionals to delegate the AUC consultation to certain clinical staff with appropriate training, but not to non-clinical personnel. We recommend that CMS revise its proposal to reflect language used in the preamble, "clinical staff," rather than "auxiliary personnel." Additionally, the ACR recommends that CMS require that the clinical staff be required to confer with the ordering professional and documented in the patient's medical record should the AUC consultation result in "not adhere" feedback. This would maintain the educational aspect of the program while allowing some flexibility for ordering professionals to delegate the AUC consultation to their clinical staff.

AAPM recommends that CMS revise its proposal to reflect language used in the preamble to allow AUC consultations by clinical staff and not auxiliary personnel.

V. Radiology Assistants

CMS is proposing to revise the physician supervision requirements so that any diagnostic test performed by a Radiologist Assistant (RA) may be furnished under, at most, a direct level of physician supervision, when performed by an RA in accordance with state law and state scope of practice rules.

AAPM supports the CMS proposal to require a direct level of physician supervision for diagnostic tests performed by a Radiologist Assistant, in accordance with state laws.

Appropriate payment for medical physics services, radiology and radiation oncology procedures is necessary to ensure that Medicare beneficiaries continue to have full access to diagnostic imaging and high quality cancer treatments. We hope that CMS will consider these issues for the 2019 Physician Fee Schedule final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2487.

Sincerely,

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