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

Re: Medicare Program: CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; CMS-1751-P

Dear Administrator Brooks-LaSure:

The American Association of Physicists in Medicine (AAPM)<sup>1</sup> is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 23, 2021 *Federal Register* notice regarding the 2022 Medicare Physician Fee Schedule (MPFS) proposed rule.

### Proposed Reductions to Radiation Oncology Payment & 2022 Conversion Factor

CMS is proposing significant payment reductions for radiation oncology services. The proposed 2022 Conversion Factor is \$33.58, a significant decrease over the final 2021 Conversion Factor of \$34.89, which was adjusted due to the Consolidated Appropriations Act, 2021 (CAA) provision that increased MPFS payment amounts for services furnished during calendar year (CY) 2021 by 3.75 percent. The expiration of the CAA increased Conversion Factor means the entire MPFS faces an immediate 3.75 percent payment reduction before taking into consideration the impact of the payment policies in the 2022 proposed rule.

In addition to the expiration of the 3.75 percent CAA Conversion Factor increase, **CMS** is proposing to reduce payments for radiation oncology services for 2022 by an additional 5 percent. This reduction is primarily due to increases in clinical labor pricing that has the effect of lowering payments to specialties that use expensive medical equipment and supplies, such as radiation oncology, under a budget neutral payment system.

<sup>&</sup>lt;sup>1</sup> 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.

Many radiation oncology procedures will experience payment decreases of 10 to 20 percent or more in CY 2022. The impact to Medical Physics Consultation codes CPT 77336 and 77370 is minus 10.2 percent and minus 8.9 percent, respectively. We are very concerned regarding excessive payment reductions proposed for 2022, especially as many providers continue to experience economic hardships related to the COVID-19 public health emergency (PHE).

While the CAA legislation prohibited CMS from using the updated figure in future Conversion Factor updates, the proposed 2022 Conversion Factor is still a decrease from the 2021 Conversion Factor and an extremely negative impact to practices still in the midst of the COVID-19 pandemic.

The AAPM urges CMS to press Congress to act and provide a positive update to the Medicare Conversion Factor in 2022 and all future years.

# **Proposed Clinical Labor Pricing Update**

CMS is proposing to update the clinical labor pricing for CY 2022, in conjunction with the final year of the medical equipment and supply pricing update. Clinical labor rates were last updated for CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available. CMS is proposing to use the methodology outlined in the 2002 MPFS final rule, which draws primarily from BLS wage data, to calculate updated clinical labor pricing.

For 2022, CMS uses the most current 2019 BLS survey data as the main source of wage data for this proposal. CMS recognizes that the BLS survey of wage data does not cover all the staff types contained in the direct practice expense database. Therefore, CMS crosswalked or extrapolated the wages for several staff types using supplementary data sources for verification whenever possible.

#### Impact of Clinical Labor Pricing Update:

Due to budget neutrality requirements, increasing the clinical labor pricing disproportionately impacts physicians and other providers with high-cost medical equipment and supplies, including radiation oncology. Analyses conducted by the American Society for Radiation Oncology (ASTRO) estimates a 30 percent increase in Medicare direct costs. Based on \$11.5 billion in allowed direct costs, the cost of updating the clinical labor pricing in 2022 is approximately \$3.5 billion.

Radiation oncology is a technology-driven specialty that utilizes medical devices and techniques to deliver radiation treatments with accuracy and precision. The technology used in radiation oncology has significantly improved in precision, efficacy, and efficiency over the years and will continue to do so. Unlike some fields of medicine where operating costs are flexible due to low fixed costs, radiation oncology operating costs are inflexible due to high fixed costs, similar to the fixed costs for robotic surgery and operating rooms, MR and PET/CT imaging devices, and facilities for inpatient care. Radiation oncology providers make significant capital investments in devices, such as linear accelerators, for the delivery of radiation therapy, and those costs are fixed over the life of the equipment. If payments change drastically, there is no way to accommodate those shifts through operating expenses without cuts elsewhere, including staff and services offered. Additionally, the costs of maintaining this equipment remain the same whether or not the equipment is used.

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in relative value units (RVUs) may not cause the amount of expenditures for the year to differ by more than \$20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, CMS

makes adjustments to preserve budget neutrality. This \$20 million "threshold" has been the same since the inception of the MPFS in 1992. **CMS should analyze the effects of implementing the clinical labor rates after no change in 20 years versus having implemented those updated rates on a more frequent basis.** 

The direct scaling factor is proposed to decrease 24 percent from 0.5916 in 2021 to 0.4468 in 2022. The practice expense component of the MPFS comprises approximately 45 percent of the total physician payment, and that percentage is fixed. Therefore, an increase in the clinical labor rates results in a shift of RVUs that were previously directed to medical equipment and supplies. Stated another way, Medicare will now reimburse 44 cents on the dollar, instead of 59 cents on the dollar, for medical equipment and supply costs. The MPFS system should provide stable and predictable reimbursement for cancer care rendered to beneficiaries. **CMS should explore options to adjust the scaling factor(s) to more appropriately reimburse for expenses incurred to treat Medicare beneficiaries.** 

The clinical labor rates have not been updated in 20 years. CMS maintains the same pricing methodology as CY 2002, including the fringe benefits multiplier of 1.366 percent. **The AAPM recommends that CMS use a current fringe benefits multiplier.** We understand that the BLS frequently publishes benefits data that could assist in updating the fringe benefits multiplier.

The AAPM encourages CMS to update clinical labor prices more frequently in the future, so as not to generate such significant payment reductions.

Clinical Labor Rate for Medical Physicist:

CMS is proposing to use the 75th percentile of the Physicist average wage data for the Medical Physicist (L152A) clinical labor type because the Agency believes this level would most closely fit with the historic wage data for this clinical labor type. A Medical Physicist is a specific type of physicist, and the available BLS wage data describes the more general category of Physicist, which is paid at a lower rate. CMS states that the 75th percentile more accurately describes the Medical Physicist clinical labor type based on how it has historically been paid. The CY 2022 proposal yields a per minute clinical labor rate of \$1.80 for a Medical Physicist.

In the proposed rule, CMS solicits comments on the proposed updated clinical labor pricing. The Agency is particularly interested in additional wage data for the clinical labor types for which they lack direct BLS wage data and make use of proxy labor categories for pricing.

It is important to note that the BLS wage data for a Physicist is <u>not</u> equivalent or representative of a Medical Physicist, even at the CMS proposed 75<sup>th</sup> percentile labor rate.

The sophistication and complexity of radiation therapy technology has increased exponentially in the past few decades. As radiation treatments have become more targeted and precise, they have also required increasingly complex equipment and processes. Computerized beam shaping systems have replaced simple blocking techniques to improve radiation field sculpting capabilities; multimodality imaging-based virtual simulation and inverse planning techniques have replaced hand calculations to improve dose conformity; rotational delivery techniques have replaced static treatments to improve treatment efficiency. The addition of stereotactic devices, on-board image guidance systems, and robotic positioning systems has improved the precision of field placement. As the accuracy and precision of radiation treatments has improved, so too have patient outcomes.<sup>2</sup>

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<sup>&</sup>lt;sup>2</sup> Citrin DE. Recent Developments in Radiotherapy. *N Engl J Med* 2017; 377:1065-1075.

As the complexity of radiation therapy treatments has grown, the work of ensuring treatment accuracy and patient safety throughout a prescribed course of treatment has also become more demanding in expertise and attention. The inherent danger posed by the use of therapeutic levels of radiation dose is managed and minimized by a Qualified Medical Physicist (QMP). Qualified Medical Physicists are tasked with ensuring that each and every radiation therapy treatment is safely and accurately delivered in accordance with the radiation oncologist's prescription. Qualified Medical Physicists have the core responsibility of ensuring the safe and proper functioning of all major medical equipment in radiation oncology and radiology; developing and guiding the implementation of standard operating procedures that govern clinical use of the equipment; consulting with the radiation oncologist to address unique patient circumstances; and providing ongoing monitoring and assessment of the technical aspects of care for each patient throughout their course of treatment.

The AAPM has conducted an annual Professional Survey Report on salary data since 1985. In 2009, the AAPM sponsored a validation study to be conducted by the Center for Health Workforce Studies at the School of Public Health at the State University of New York – Albany (SUNY). The study was initiated to validate the accuracy of the data collected by the American Institute of Physics (AIP) for the AAPM's annual Professional Survey. The study confirmed the accuracy of the medical physicist salary data collected in 2010 by the AIP and published in the AAPM annual Professional Information Report.

The AAPM recommends that CMS utilize the CY 2020 Professional Survey Report on salary data to determine the updated clinical labor rate per minute for a Qualified Medical Physicist.

Further, it is important to note that CMS utilized the AAPM 2005 salary data, inflated to 2006, when CMS updated the clinical labor wage rates for CY 2002.

Specifically, the AAPM recommends that the Medical Physicist clinical labor rate be updated to \$2.25 per minute.

This calculation is based on the weighted median salary of certified Qualified Medical Physicists with a Masters or Ph.D. degree multiplied by the CMS proposed benefits factor of 1.366. Please note that this rate does not include the CMS proposed conversion to 2021 dollars using the Medicare Economic Index.

Based on the AAPM recommendation, a revised clinical labor rate for a Medical Physicist (L152A) will also require an update for the mixed clinical labor staff type of Medical Dosimetrist/Medical Physicist (L107A).

#### Implementation Timeline:

Given the issues noted above, the AAPM believes the current clinical labor proposal requires additional analysis and modifications prior to implementation. There is further work to ensure accurate data is used and appropriate methodological steps are taken for implementation. It is important to note that CY 2022 will be the fourth and final transition year of the update to medical equipment and supply items—a proposal that also yielded significant shifts in radiation oncology payment rates. **CMS should fully consider stakeholders' comments about the methodology and impact of the clinical labor price update and whether it would be more appropriate to publish an updated clinical labor proposal for CY 2023 rulemaking.** 

Additionally, CMS requested comment on whether to implement a four-year transition to the new clinical labor cost data. There is precedent for a phased transition for significant MPFS changes, across several calendar years. CMS utilized a 4-year transition for the market-based medical equipment and supply pricing update concluding in CY 2022. CMS also utilized a 4-year transition, starting in 2010, for the new practice expense methodology.

The AAPM recommends that CMS implement a 4-year transition for updated clinical labor rates beginning January 1, 2023.

### **Removal of PET National Coverage Decision**

CMS is proposing to remove the national coverage determination (NCD) for position emission tomography (PET) scans (i.e., NCD 220.6). Removing the NCD would defer coverage decisions to local Medicare Administrative Contractors (MACs). The existing NCD for PET was last updated in 2013 and requires separate NCDs for every non-oncologic indication for PET scans. Since 2013, new non-oncologic PET agents have been approved by the FDA and multiple professional medical societies have published guidelines relevant to appropriate use of these agents. CMS believes that allowing local contractors the discretion to consider coverage would allow Medicare beneficiaries greater access to PET scans for non-oncologic indications. We agree that non-oncologic PET coverage should be addressed by local MACs and in accordance with the American College of Radiology (ACR) and Society of Nuclear Medicine and Molecular Imaging (SNMMI) guidelines.

The AAPM recommends that CMS remove the national coverage determination (NCD 220.6) for non-oncologic position emission tomography (PET) scans.

#### Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS is proposing to begin the Appropriate Use Criteria (AUC) claims processing system edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the PHE for COVID-19 ends. This flexible effective date is intended to take into account the impact the PHE for COVID-19 has had and may continue to have on practitioners, providers and beneficiaries.

The AAPM supports the CMS proposal to begin the Appropriate Use Criteria (AUC) claims processing system edits and payment penalty phase of the program on the later of January 1, 2023, or the January 1 of the year after the year in which the public health emergency (PHE) for COVID-19 ends.

## **Expiration of Public Health Emergency Flexibilities for Direct Supervision Requirements**

Direct supervision requires the immediate availability of the supervising physician or other practitioner, but the professional need not be present in the same room during the service. Immediate availability has been interpreted to mean in-person, physical availability (not virtual).

During the COVID-19 PHE, CMS changed the definition of "direct supervision" as it pertains to the supervision of diagnostic tests, physicians' services, and some hospital outpatient services to allow the supervising professional to be immediately available through virtual presence using real-time audio/video technology, instead of requiring their physical presence. In the 2021 MPFS final rule, CMS continued this policy through the end of the PHE for COVID-19 or December 31, 2021, whichever comes later.

In the 2022 MPFS proposed rule, CMS seeks information on whether this flexibility should be continued beyond the latter of the end of the PHE for COVID-19 or 2021.

The AAPM believes that direct supervision is the proper standard for delivery of radiation therapy and supports its continued use through real-time, interactive audio and video technology for the duration of the PHE. However, we do <u>not</u> support continued use of real-time, interactive audio and video technology once the PHE has concluded. Due to the irreversible nature of radiation therapy, it is critical that practices provide direct supervision to ensure the continued delivery of safe and high-quality radiation therapy services.

The AAPM does <u>not</u> support continued use of real-time, interactive audio and video technology once the COVID-19 public health emergency (PHE) has concluded. CMS should revert back to the pre-COVID definition and interpretation of Direct Supervision.

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 2022 Medicare Physician Fee Schedule final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2503.

Sincerely,

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