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October 5, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Re: CMS-1734-P—Medicare Program: CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc.

Dear Administrator Verma:

As the premier trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the referenced Centers for Medicare & Medicaid Services Proposed Rule on Medicare payment rates and policies for services paid under the Physician Fee Schedule (PFS).

Medical imaging is essential to the screening, diagnosis, staging, surveillance, and therapy monitoring of many diseases and other medical conditions. For this reason, CMS should recognize the invaluable role of medical imaging across all Medicare payment systems.

Our comments address the following:

1. CMS should use its own authority to mitigate the impact of the E&M policy changes,
2. CMS should ensure appropriate payment for high intensity focused ultrasound ablation procedures,
3. CMS should retire the National Coverage Determination (NCD) for computed tomography colonography (CTC),
4. MITA supports removal of the NCD for FDG PET for inflammation and infection, and
5. CMS should recognize how the pandemic affects current and future rate-setting.

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1. CMS should use its own authority to mitigate the impact of the E&M policy changes

The healthcare sector will not immediately recover from the COVID-19 pandemic and its economic consequences. In order to not compound the access, economic, and innovation challenges facing beneficiaries, providers, and medical technology manufacturers during the pandemic and its recovery phase, CMS should not implement new policies which result in crippling payment cuts. A strong recovery will promote public health, enable beneficiary access, and support adoption of innovative medical imaging technologies such as artificial intelligence platforms, novel radiotracers, and new scanners for the future.

The forthcoming changes to Evaluation and Management (E&M) payments will have a profoundly negative impact on specialty physicians, including radiologists, and other health care professionals that provide medical imaging services to Medicare beneficiaries. Radiology, in particular, will be devastated by these payment cuts with a reduction of greater than 10%. There are steps that CMS can take in the CY 2021 PFS final rule that would mitigate the disastrous consequences of this policy. In the CY 2021 PFS final rule, CMS should:

- Use its authority to waive budget neutrality for the duration of the Public Health Emergency declaration, or
- Delay the implementation of these policy changes until a future year and work with stakeholders to determine a more equitable solution, and
- Delay or cancel implementation of the GPC1X add-on code,

2. CMS should ensure appropriate payment for high intensity focused ultrasound ablation procedures

We believe the Agency misinterpreted the physician work survey completed for the RUC and has therefore incorrectly estimated the appropriate work RVU for 558XX. Specifically, the Agency states the RUC recommendation of 20.00 work RVU was the median of the physician work survey. However, the RUC recommendation was the 25th% survey work RVU, not the median. The RUC specifically choose the 25th% work RVU, as they often do, to account for possible misestimation of work RVUs by survey respondents. By recommending the 25th% work RVU the RUC already adjusted the work RVU ratio to time to provide more appropriate relativity to similar services, such as the two key reference services of 55840 (21.36 work RVU, same intra-service work time of 180 minutes) and 55873 (13.60, 100 minutes intra-service work time). In fact, the work RVU of 20.00 is appropriately relative to 55840 with the same intra-service time and the only difference being with inpatient visits for 55840. However, 558XX is much more intense and requires high precision and focus by the physician compared to a prostatectomy.

The survey conducted by the American Urological Association (AUA) represents the best estimation of work for HIFU. It was completed by 30 surgeons with extensive training and experience in providing the service. Unlike many newer CPT codes, HIFU is a long-established service that has been extensively performed outside the US and has been performed thousands of time already inside the US by trained physicians. These providers have the greatest expertise in the procedure and have a thorough and well-grounded knowledge of the service, along with the typical patient, and the time and intensity requirements to perform the service. We believe their time and work estimates to be accurate and by recommending a work RVU of 17.73 well below the survey 25th% response, the Agency has misinterpreted the survey results and the RUC recommendations.

Furthermore, the comparison to CPT code 69930 is not clinically appropriate or relevant to HIFU. 69930 is a cochlear implant procedure performed primarily by otolaryngologists on a pediatric population while HIFU is performed primarily by urologists for older male patients with prostate cancer. These patient populations are not comparable and the procedures themselves are not comparable and, therefore, not appropriate for crosswalks.

We urge CMS to revise their proposed work RVU of 17.73 and accept the RUC recommended 25th% work RVU of 20.00 for 558XX.

3. CMS should retire the National Coverage Determination (NCD) for computed tomography colonography (CTC)

In this proposed rule, CMS identifies several criteria under which an older National Coverage Determination (NCD) may be retired and proposes to retire the NCDs for several medical services. We believe that the NCD for computed tomography colonography (CTC)¹ should be added to this list and retired, enabling local Medicare contractors to make their own coverage decisions.

The value of colorectal cancer screening has become more apparent in recent years, in particular the maxim that “the best test is the one that gets done.” The United States Preventive Services Task Force (USPSTF) currently recommends “screening for colorectal cancer starting at age 50 years and continuing until age 75 years.”² CRC is the second most common cancer diagnosed in United States and the third leading cause of cancer death even though it has a roughly 90% 5-year survival rate when detected early.³ Unfortunately, as indicated in a May 2015 report from the Centers for Disease Control and Prevention (CDC), CRC screening is dramatically underutilized.⁴

Additionally, CRC is somewhat unique in that certain tests—including CTC—can detect it in a pre-cancerous stage. For this reason, the USPSTF cited in its 2016 final recommendation statement for CRC, “the best screening test is the one that gets done, and the USPSTF concludes that maximizing the total proportion of the eligible population that receives screening will result in the greatest reduction in colorectal cancer deaths.” CRC detection rates with CTC were essentially identical to those achieved with optical colonoscopy. CTC and optical colonoscopy are the only two methods of CRC prevention, versus alternatives that are CRC diagnostic.⁵

CMS has been lagging current coverage practices by continuing to not cover CTC. CTC is widely available in the USA and covered by over 100 commercial insurance plans, including all the major national insurers such as United, Aetna, Anthem/Wellpoint, Humana, Cigna. Retiring this NCD will enable local Medicare contractors to issue their own coverage decisions, potentially increasing access to this service.

¹ [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+\(CTC\)+for+Colorectal+Cancer](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=220&NcaName=Screening+Computed+Tomography+Colonography+(CTC)+for+Colorectal+Cancer)

² <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/colorectal-cancer-screening2?ds=1&s=colorectal>

³ <http://www.cancer.org/cancer/colonandrectumcancer/detailedguide/colorectal-cancer-survival-rates>

⁴ https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6417a4.htm?s_cid=mm6417a4_w

Finally, the COVID-19 pandemic has caused a significant backlog in screening exams. Expanding the CRC screening options available to Medicare beneficiaries to include CTC will help to draw down this backlog, keeping patients on track for their routine screening exams.

4. MITA supports removal of the NCD for FDG PET for inflammation and infection

MITA supports retiring section 220.6.16 of the National Coverage Determinations (NCD) Manual, “FDG PET for Inflammation and Infection,” and allow coverage at the discretion of the Medicare Administrative Contractors (MACs). We believe the clinical evidence supports MAC coverage of these indications, along with MAC discretion to cover other FDA approved positron emission tomography (PET) imaging agents that are not subject to an existing NCD.

Additionally, we recommend that CMS update its criteria for expedited retirement of NCDs to allow for the retirement of NCDs that are more than five years old, or for which there is new clinical evidence or FDA authorization that causes the NCD to be outdated or to restrict beneficiary access to medically necessary items and services. This will provide CMS with much-needed flexibility given the fast pace of health care innovation in this space.

Detail elucidating specific changes to the NCD Manual, Section 220.6, as well as the Preamble have been provided under separate comments by the MITA PET Coverage and Coding Committee.

5. CMS should recognize how the pandemic affects current and future rate-setting

It is becoming clear that the COVID-19 pandemic has resulted in significant changes to utilization patterns for healthcare services, including imaging. CMS should take steps to ensure that its rate-setting methodologies reflect the new realities of care. In particular, CMS should study the impact of the resources required for implementing new standards of infection control procedures on the practice expense assumptions for a wide variety of services, including medical imaging exams, physicians offices visits, surgical procedures, etc. Finally, CMS should study the validity of year 2020 data for future rate-setting.

We also believe that CMS should value and include on the PFS for CY 2021 HCPCS code 99072, *Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease*. This code was created by the CPT Editorial Panel effective September 8, 2020 to capture additional costs for practice expenses related to services delivered in non-facility settings during the PHE. These costs, including direct supplies, greater equipment cleaning and use time, and clinical labor time, can be significantly more than usual for imaging services. These services require additional cleaning and safety supplies and time to ensure proper infection control. We urge CMS to value this HCPCS code in line with the RUC recommendations.

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If you have any questions, please contact Peter Weems at 703-389-1614 or by email at pweems@medicalimaging.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.