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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: Comments on CMS-1736-P—Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Addition of New Categories for Hospital Outpatient Department Prior Authorization Process; 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 (CMS) Proposed Rule on Medicare payment rates and policies for services paid under the Hospital Outpatient Prospective Payment System (HOPPS).

Our comments address the following:

1. Prior to CY 2022 rulemaking, CMS should initiate a process to develop a better methodology for accurately capturing hospitals' capital costs in imaging services in hospital outpatient departments,
2. CMS should remove provider claims using the "square feet" cost allocation method to calculate cost-to-charge ratios (CCRs) associated with CT and MRI procedures in the CY 2021 final rule and require providers to report costs via the direct assign or dollar value methodologies moving forward,
3. CMS should discontinue packaging of diagnostic imaging drugs and pay separately for such products immediately,
4. CMS should ensure appropriate payment for prostate high-intensity focused ultrasound,
5. CMS should ensure appropriate payment for SPECT imaging,
6. CMS should ensure appropriate payment for cardiac CT services, and
7. CMS should recognize how the pandemic will affect current and future rate-setting.

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1. Prior to CY 2022 rulemaking, CMS should initiate a process to develop a better methodology for accurately capturing hospitals' capital costs in imaging services in hospital outpatient departments

Current cost-reporting practices do not accurately reflect a hospital's true cost of delivering imaging services. Cost-reporting is currently administratively burdensome and overly complicated, meaning that some costs are not reported accurately by some providers. This is further compounded by payment policies such as packaging and comprehensive APCs which make capturing and reporting costs even more challenging for hospitals.

MITA urges CMS to work with stakeholders prior to the release of the CY 2022 HOPPS proposed rule on detailed instructions to hospitals that address the appropriate reporting of nonstandard cost center codes. This would improve the accuracy of the cost center data used to calculate CT and MRI CCRs applicable to the payment rates calculated under HOPPS.

It is our belief that because costs are not being accurately reported, that money is not being properly accounted for within the payment system, as evidenced by the downward payment trajectory of imaging APCs over the last several years. This presents potential challenges to hospital economics regarding the purchase of imaging equipment. This has been borne out during the COVID-19 public health emergency where beneficiary access at the point of care for very sick individuals was not always available in a timely manner.

MITA is concerned about the impact these costing requirements have on the continued access to medical imaging services for Medicare beneficiaries. For example, it is well established in the peer reviewed literature that cardiac disease is very prevalent in the Medicare beneficiary population. Yet, we have seen patterns of decreased HOPPS payment specifically with cardiac computed tomography angiography (CCTA) and echography which are important diagnostic tests to identify the extent of the disease and inform care pathways. However, with the HOPPS system, payment for CCTA has decreased 30% over the last three years (cumulatively). For echocardiography, similar trends exist. Without complete diagnostic information, precise care pathways and optimal outcomes are at risk. CMS should implement sound payment methodologies which effectively capture hospitals' costs in furnishing imaging services.

2. CMS should remove provider claims using the "square feet" cost allocation method to calculate cost-to-charge ratios (CCRs) associated with CT and MRI procedures in the CY 2021 final rule and require providers to report costs via the direct assign or dollar value methodologies moving forward

MITA continues to support excluding claims from providers using a square-foot, area-based cost allocation method to calculate CT and MRI APCs. Valid CCRs are critical to ensuring appropriate payments under the HOPPS and we believe that CMS's current policy improves the validity of the CCRs. MITA also supports the Agency's determination to direct hospitals to avoid using area-based cost allocation method in its cost reports. MITA would be happy to join with CMS in this education process and work with the Agency in the dissemination of information and materials to hospitals regarding the appropriate allocation methods for capital costs.

This is particularly important given the additional flaws CMS has previously acknowledged. In its proposed and final FY 2016 Inpatient Prospective Payment System (IPPS) rules, CMS described inconsistencies in the Healthcare Cost Report Information System (HCRIS) that may result in invalid Radiology and Other Services CCRs. These inconsistencies result from the way hospitals allocate costs to nonstandard cost centers and are compounded by the process CMS applies to map and "roll up" each

nonstandard code to standard cost centers. Although CMS did not raise these cost data issues in past rulemaking, the Agency did note that CCRs are allocated for each cost center “using hospital-specific data from [HCRIS].”

In light of the ongoing issues with CCR calculations, MITA urges CMS to continue to work with stakeholders on detailed instructions to hospitals that address the appropriate reporting of nonstandard cost center codes. This would improve the accuracy of the cost center data used to calculate CT and MRI CCRs applicable to the payment rates calculated under HOPPS. We also believe that in order to obtain the most accurate cost-reporting data for CT and MRI cost centers, CMS could solve for the issue by mandating that providers report via one of the preferred methodologies; direct assign or dollar value. We encourage CMS to make one of these two methodologies mandatory in future cost reports and maintain the exclusion of “square feet” claims until such time that the complete data is available for rate-setting.

3. CMS should discontinue packaging of diagnostic imaging drugs and pay separately for such products immediately

CMS should discontinue packaging of diagnostic imaging drugs and pay separately for such products immediately. In so doing, CMS should consider the following:

- Two APC panel have recommended separate payment of diagnostic radiopharmaceuticals,
- MedPAC has recognized packaging of certain drugs may impact access, and
- Specific language for resolution has been provided in HR 3772

Advanced imaging diagnostic radiopharmaceuticals continue to be inappropriately packaged in the Medicare hospital outpatient setting. Under the current inequitable payment methodology, many hospitals are unable to cover the cost of newer, targeted diagnostic radiopharmaceuticals. They should be treated like other FDA approved drugs and paid separately under HOPPS.

After a three-year period of separate or “pass-through” reimbursement, CMS deems diagnostic radiopharmaceuticals as supplies and reimburses only as part of a packaged reimbursement rate (APC) far below actual costs. Packaging of diagnostic radiopharmaceuticals harms Medicare beneficiaries by imposing an artificial barrier in the hospital outpatient setting. The Agency’s position that packaging would incentivize hospitals to use a cheaper alternative does not apply to newer diagnostic radiopharmaceuticals. These products are often the only available diagnostic and are not interchangeable with other products or services. Therefore, Medicare beneficiaries may not have access to diagnostics which provide important adjunctive clinical information which may impact their treatment and outcomes.

Further, the HOPPS packaging methodology of diagnostic radiopharmaceuticals does not adequately capture the cost of diagnostic radiopharmaceuticals. Our Member companies have provided to CMS evidence of hospitals discontinuing or never adopting these clinically advanced imaging procedures due to artificially low Medicare payment rates. As a result, less precise diagnostic information may lead to suboptimal clinical decisions and outcomes for Medicare beneficiaries.

On August 31, 2020, the Advisory Panel on Hospital Outpatient Payment recommended that CMS pay separately for all diagnostic radiopharmaceuticals. This is the second such Panel to support separate payment of diagnostic radiopharmaceuticals.

The most recent MedPAC report (June 2020) discussed separately payable drugs. In this report, MedPAC stated, “Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit...” Given the specific utility of diagnostic drugs, it is our belief that these products are the reason for the visit.

The MedPAC Report addresses for the first time (in Chapter 6) Medicare’s packaged payment policies in the OPPTS, including directly addressing the characteristics of “ancillary items” that MedPAC staff believe should not be packaged. First, after repeatedly noting that “not all ancillary items should be packaged,” MedPAC explains that packaging costly or infrequently used “ancillary items” can pose an “excessive” financial risk to hospitals that will impact patient access.

We believe the MedPAC example is analogous to what occurs to diagnostic radiopharmaceuticals under packaging policies. These products are low volume and comparatively expensive to other drugs included in the assigned APC. The newer generation, non-generic diagnostics are the drugs most egregiously impacted by the methodology under which CMS averages and bundles the nuclear medicine APCs.

These policies harm Medicare beneficiaries by putting strong financial pressure on providers to avoid the use of certain diagnostic radiopharmaceuticals. As MedPAC notes on page 169 (PDF page 189) this puts “providers at excessive financial risk, which can lead them to avoid infrequently used or high-cost drugs and adversely affect access to treatments that may improve patient care, which, in turn, can adversely affect incentives for drug innovation.”

Legislation currently being considered by Congress (HR 3772 - the Medicare Diagnostic Radiopharmaceutical Payment Equity Act) would require CMS pay separately for diagnostic radiopharmaceuticals approved by the FDA on or after January 1, 2008 and have a per day cost that meets or exceeds \$500. We support this legislation and request CMS use their authority to adopt the provisions of the bill.

4. CMS should ensure appropriate payment for prostate high-intensity focused ultrasound

We strongly recommend that CMS reassign Focused Ultrasound Ablation of the prostate (C9747, 55880) to Urology APC Level 6 from its current Level 5. Focused ultrasound ablation of prostate cancer produces disease control equivalent to that of prostatectomy, cryosurgery, and radiation therapy, but with a much lower side effect profile. However, at the payment assigned to Level 5, this procedure will not be offered to the majority of Medicare beneficiaries given that the costs of performing the procedure are dramatically higher than the proposed payment level.

Cryosurgery (55873) is a similar minimally invasive procedure used to treat prostate cancer performed on an outpatient basis. C9747 has been assigned to Level 5 since the 2019 final rule. However, 55873 is assigned to Level 6. From a clinical point of view, these two procedures, which require similar resources to treat the same disease, should be assigned to the same APC. Effective January 1, 2021, the AMA is issuing new CPT code 55880 (*Ablation of malignant prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound guidance*). As indicated in the description, this new CPT code is specific for prostate cancer while C9747 does not specify an indication beyond ablation of prostate. Because HIFU for malignancy is similar to 55873 (prostate cryoablation), clinically and in terms of cost, and both procedures have the same indication according to the NCCN guidelines, they should be assigned to the same APC for parity. 55873 cannot be assigned to APC Level 5 without violating the “two times” rule. Therefore, the only way to keep these two similar procedures in the same APC is to assign 55880 to APC Level 6.

We urge CMS to reassign 55880 (*Ablation of malignant prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound guidance*) to APC Level 6, thereby ensuring Medicare beneficiary access to this innovative procedure.

5. CMS should ensure appropriate payment for SPECT imaging

Given the Agency's proposed crosswalk of SPECT CPT Code 78803 to APC group 5592, we are concerned that the associated 60% payment rate reduction seriously undervalues the radiopharmaceuticals utilized in conjunction with this CPT Code, which will result in reduced access to important diagnostic care. In light of the CPT Editorial Panel's previous decision to delete multiple SPECT codes, 78803 became more generic in nature, covering a wide variety of radiopharmaceuticals and organs. In response to last year's proposed rule, we and other stakeholders weighed in on this point, and CMS responded appropriately, changing its proposal then from a cross walk to APC 5592 to APC 5593. As a result, the current payment rate for SPECT Code 78803 through APC 5593 is \$1,272.05. If CMS finalizes its proposal, the payment rate for SPECT Code 78803 will be slashed to \$501.45. We are concerned that such a drastic cut will deny reasonable and necessary medical care to the Medicare population. CMS should crosswalk SPECT CPT Code 78803 to its current APC 5593 to ensure proper patient access to these innovative radiopharmaceuticals.

6. CMS should ensure appropriate payment for cardiac CT services

MITA is concerned with the methodologies used to set payment rates for cardiac CT/CTA services that fall under HCPCS codes 75572-75574 and are proposed to continue assignment to APC 5571 (Level 1 Imaging with Contrast). Payment for these services have declined by almost 30% in the past three years and further deterioration may impact beneficiary access to procedures that have been proven to improve diagnostic capabilities and patient outcomes through robust randomized clinical trials.

Cardiac CT/CTA procedures are unlike tradition CT services in that they require more time, specially trained technologists, administration of vasoactive medications, and patient monitoring post-procedure. Patients must be evaluated and screened prior to the administration of vasoactive medications to avoid complications and the procedures require electrophysiologic monitoring during the procedure via electrocardiogram. We do not believe the current cost data accurately reflects these additional costs and is being artificially deflated due to reporting under the CT cost center, where the additional costs mentioned are not captured. As payment rates for these services continue to decline, we are concerned that Medicare beneficiaries will lose access to proven option for diagnosing cardiac disease.

7. CMS should recognize how the pandemic will affect 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.

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If you have any questions, please contact Peter Weems at 703-841-3238 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.