



**MITA**<sup>®</sup>  
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September 11, 2023

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

**Re: CMS–1793–P—Medicare Program: Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022**

Dear Administrator Brooks-LaSure:

As the premier trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) is submitting the following comments on the referenced proposed rule titled “Medicare Program: Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022.”

Under the Hospital Outpatient Prospective Payment System (HOPPS), CMS generally sets payment rates for separately payable drugs under section 1833(t)(14)(A) of the Social Security Act (the Act). In the calendar year (CY) 2018 HOPPS final rule, CMS reexamined the appropriateness of paying the ASP plus 6% for drugs acquired through the 340B Program. Consequently, CMS adopted a policy, beginning in 2018, generally to pay an adjusted amount of ASP minus 22.5% for certain separately payable drugs acquired through the 340B Program. From January 1, 2018, through September 27, 2022, under HOPPS CMS generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5%.

On December 27, 2018, in the case of *American Hospital Association v. Azar*, the United States District Court for the District of Columbia concluded that the Secretary exceeded his statutory authority by adjusting payment rates for drugs acquired under the 340B Program to ASP minus 22.5% for CY 2018. The District Court subsequently came to the same conclusion for CY 2019. The Supreme Court declined to opine on the appropriate remedy and remanded the case to the D.C. Circuit, which in turn remanded it to the District Court.

On January 10, 2023, the District Court issued a remand without vacatur to give CMS the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final HOPPS rules for CY 2018 through CY 2022. The agency complied with the District Court's September 28, 2022, decision by uploading revised OPSS drug files to pay the default rate (generally ASP plus 6%) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.

In this proposed rule, CMS believes that the best way to remedy its payment policy for 340B-acquired drugs for the period from CY 2018 through September 27th of CY 2022, is to, beginning in CY 2025, reduce all payments for non-drug items and services to all HOPPS providers, except new providers, by 0.5% each year until the total offset is reached (approximately 16 years).

MITA is deeply concerned about imposition of another automatic 0.5% payment reduction on HOPPS services for the next 16 years, in addition to the 2.0% sequestration reduction that is now reinstated post the Public Health Emergency (PHE). Per the KaufmanHall National Hospital Flash Reports, a sampling from more than 1,300 hospitals on a recurring monthly basis from Syntellis Performance Solutions, (<https://www.kaufmanhall.com/insights-reports/national-hospital-flash-report>), hospitals continue to struggle to regain the volume of outpatient services provided prior to the COVID-19 PHE, including medical imaging services. Medical imaging services have faced numerous payment cuts in recent years and many of the services are now subjected to some level of conditional packaging on the HOPPS fee schedule increasing the lack of claims data that CMS has available for annual HOPPS rate setting due to hospital's internal policies regarding submitting a charge on a Medicare claim for a packaged service. This is causing some imaging APC payment rates to fall or stay basically the same and therefore also decrease in adjusted dollars due to inflation. Another long-term cut will only inhibit hospitals' ability to invest in new technologies to continue or expand patient care services, creating new barriers to access for Medicare beneficiaries, specifically in certain geographic areas – i.e., the Midwest and the South.

We are also concerned about the effect of this policy on new items and services that were not available and thus not reimbursed by the HOPPS fee schedule during the time period that CMS is now required to remedy. New imaging technologies, including advanced AI and PET applications, will be coming to market in the coming years. Since these technologies were not available for use and not reimbursed at APC levels that occurred due to reductions in reimbursement for 340B-acquired drugs during CY 2018 to CY 2022—and therefore did not benefit from any increased payments during that time—MITA does not believe that the 0.5% payment cut should be applied to these new items and services. Unfairly penalizing the use of new technologies would present an undue barrier to beneficiary access of these items and services.

MITA urges CMS to create a system that allows for items and services that are new since October 1, 2022, to not be subjected to the 0.5% reduction. This could be accomplished with the creation of a new status indicator that would alert the Medicare Administrative Contractors (MACs) to the service being new post-October 2022 and therefore, not subjected to the 0.5% reduction, which we are assuming would be adjudicated at the MAC level using the same methods applied to take the adjustment for sequestration.

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If you have any questions, please contact Peter Weems, Senior Director of Policy & Strategy, at 703-841-3238 or by email at [pweems@medicalimaging.org](mailto:pweems@medicalimaging.org).

Sincerely,



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.*