August 31, 2026

Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard Baltimore, MD 21244

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program Proposed Rule for Calendar Year 2027 (CMS-1850-P)

Dear Administrator Oz:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group established 20 years ago and comprising more than 150 institutions from across the health care spectrum to promote the understanding and adoption of personalized medicine concepts, services, and products, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the CY 2027 Outpatient Prospective Payment System (OPPS) proposed rule.[i] While PMC recognizes there are numerous important payment issues addressed in the CY 2027 OPPS Proposed Rule, our comments focus on policies that impact beneficiary access to cell and gene therapies, targeted radiopharmaceuticals products, breakthrough devices, and software-based technologies that support personalized medicine.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests and individual details about a person's health to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own responses to the Medicare CY 2027 OPPS Proposed Rule and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of

personalized medicine can advance, and are not intended to adversely impact the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to the proposed rule.

Supporting Delivery of Cell and Gene Therapies in the Outpatient Setting

CAR T-cell therapy represents a significant advancement in personalized medicine. Some cancer patients with very poor prognoses have experienced life-improving and life-extending outcomes resulting from CAR T-cell therapy. The CAR T-cell therapies already on the market have had a profound impact on the lives of patients with certain forms of lymphoma, leukemia, and multiple myeloma. With CAR T-cell therapies being tested in hundreds of clinical trials, the promise of other cell and gene therapies provides hope for many patients with hard-to-treat diseases.

Since CAR T-cell therapies became available in the inpatient setting, PMC has supported CMS' efforts to facilitate access to them by establishing a permanent reimbursement solution that is formulated in a manner reflecting the true expenses associated with patient care.[ii] Although most CAR T-cell therapies have been delivered in the inpatient setting, advancements in treatment protocols and improvements in patient management are making outpatient administration increasingly feasible.[iii] When offered in the outpatient setting, CAR T-cell therapies are subject to Medicare reimbursement under CMS' OPPS.

Under the OPPS, reimbursement levels for treatments and their associated administration costs can be included under a comprehensive Ambulatory Payment Classification Group, or C-APC. PMC previously supported CMS' proposal to exclude certain qualifying cell and gene therapies, including CAR T-cell therapies, from C-APC packaging for one year in CY 2025 and urged CMS not to create a new C-APC packaging reimbursement for CAR T-cell therapies and their associated administration services. Packaging CAR T-cell therapy into a C-APC would pay all therapies the same, regardless of the cost to a hospital of a specific product. **PMC appreciates CMS excluding CAR T and other qualifying cell and gene therapies from C-APC packaging reimbursement in CY 2026 and for proposing to continue the exclusion in CY 2027 and future years. Doing so will support outpatient administration, which is especially important for patients in rural areas and communities with limited access to specialized inpatient facilities.**

Reimbursing for Targeted Radiopharmaceutical Products

PMC previously supported CMS' proposal to unbundle payment for certain diagnostic radiopharmaceutical products.[iv] CMS' prior policy of bundling payment for diagnostic radiopharmaceuticals with payment for their associated diagnostic test or procedure undermined access when hospitals declined to offer certain services in the outpatient setting due to inadequate reimbursement from the bundled payment methodology. The payment change was especially important for patient access to targeted diagnostic radiopharmaceuticals, also known as precision diagnostic radiopharmaceuticals, which are crucial to ensuring that Medicare beneficiaries receive the most effective and efficient treatments. For example, beta amyloid positron emission tomography (PET) imaging remains a critical tool for diagnosing Alzheimer's disease (AD), ruling out a diagnosis of AD, and evaluating whether and how certain treatments may work for a patient. Unbundled payments help ensure that patients can access advanced imaging in the hospital outpatient setting for AD and a number of other serious health conditions, including certain cancers, Parkinson's disease, and cardiovascular disease.
For CY 2026 CMS proposed policies for drugs, biologics, and radiopharmaceuticals which are reimbursed either based on Average Sales Price (ASP) +6 percent or through packaging into APCs under OPPS. For patients, the method of reimbursement determines both provider willingness to furnish treatment and beneficiary cost-sharing obligations. CMS recognizes in the CY 2027 proposed rule that the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been successfully implemented for other separately payable drugs and biologics, as well as for therapeutic

radiopharmaceuticals. However, CMS proposes to continue using mean unit cost (MUC) in CY 2027 as the payment methodology for established separately payable diagnostic radiopharmaceuticals with per-day costs above the CY 2027 packaging threshold of $665.

ASP offers more predictable and transparent reimbursement compared to MUC, which is critical for improving patient access in the outpatient setting. **PMC encourages CMS to expand upon its earlier effort to increase utilization of diagnostic radiopharmaceuticals in the outpatient setting by aligning the payment rate for established separately payable diagnostic radiopharmaceuticals to ASP, which the agency is already doing for new diagnostic radiopharmaceuticals with and without pass-through status**.

Shifting Pass-Through Payment Policy for Breakthrough Devices

Medicare transitional pass-through payment (TPTP) provides supplemental reimbursement that is intended to facilitate adoption of new devices in the outpatient setting. CMS has historically evaluated applications for TPTPs based on newness, cost, and evidence of substantial clinical improvement (SCI), however, in 2020 CMS introduced an alternative pathway to allow FDA-designated breakthrough devices to qualify for supplemental reimbursement without demonstrating SCI to address situations in which payment may be inadequate for cases involving a new technology.

FDA's breakthrough device designation is intended to accelerate patient access to innovative technologies. Of the 198 breakthrough devices authorized for marketing by the FDA, an increasing number are supporting personalized medicine, including advanced digital diagnostics, remote patient monitoring systems, and other Artificial Intelligence (AI)-enabled technologies.[v] Breakthrough devices involve years of development, significant investment, commitment of resources, running of clinical trials, and market launch preparations. The alternative pathway for breakthrough devices was intended to reduce the evidentiary burden for demonstrating SCI because breakthrough devices often face a longer timeline to achieve reimbursement, including coverage by Medicare and other payers. PMC is concerned that the CY 2027 OPPS proposed rule would eliminate the alternative pathway for breakthrough device applications.

The alternative pathway has helped bridge the gap between FDA authorization and early adoption of breakthrough devices in the hospital outpatient setting, with many of the devices intended for the treatment of patients with life-threatening or life-altering conditions. Providers rely on pathways like these to provide patient access to new and innovative technologies. Requiring breakthrough devices to meet the same criteria for TPTP status as non-breakthrough devices could have significant implications for the availability of innovative technologies for patients. Innovators will face less predictability around earlier outpatient utilization without additional payment. Potential delays in clinical adoption of higher-cost technologies may also result from the inability of providers to absorb the expense without support. Therefore, **PMC respectfully requests that CMS reconsider the proposal requiring that all applicants for OPPS device pass-through payments, including breakthrough devices, demonstrate evidence of SCI as criteria for payment.**

Developing Payment Policy for Software as a Medical Service (SaMS)

In recent years, there have been rapid developments in the use of software-based technologies to support clinical decision-making in the outpatient and physician office settings. More services have begun to include innovative technology such as software algorithms and AI. With regard to personalized medicine, innovative technology such as software algorithms and AI-based tools may provide opportunities to assist in the interpretation of patient data and enable more cost-effective health care delivery.[vi]

Over the past decade, clinical laboratories have led the development of diagnostic tests that pair laboratory analyses (e.g., genomic sequencing, gene expression profiling, immunoassays, and digital pathology) with

sophisticated algorithms including machine learning and other AI methods. The algorithmic component of these tests is developed, analytically validated, clinically validated, and continuously monitored inside a clinical laboratory certified by CLIA to perform high-complexity testing services, under the same quality system that governs every other phase of the test. For many conditions, particularly cancer, algorithmic analysis can convert data such as a whole transcriptome, a multi-gene panel, or a digitized whole-slide image into more advanced, more clinically actionable results.

In the CY 2026 OPPS Proposed Rule, CMS acknowledged that innovative software applications and AI-based tools are not well accounted for in CMS' APC-based system and that hospitals and other providers face difficulty aligning acquisition costs and reimbursement. In previous comments PMC called on CMS to develop a clear, coherent, and sustainable framework for these services across Medicare's payment systems. However, we believe the CY 2027 proposed Software as a Medical Service (SaMS) framework could result in confusion between hospitals, providers, and laboratories on furnishing and billing for services, in some cases limiting patient access, and impose coinsurance on tests that today carry none.

CMS proposes to formally recognize SaMS as a distinct category of medical technology in CY 2027. SaMS refers to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. Within that framework, CMS defines "SaMS analyses performed on laboratory tests" as subsequent stand-alone algorithmic analyses that are separate from a CLIA-certified laboratory's examination of human material. CMS proposes to reclassify 10 Healthcare Common Procedure Coding System (HCPCS) codes the agency has identified as "SaMS analyses performed on laboratory tests" and remove those codes from the Clinical Laboratory Fee Schedule (CLFS) and to pay for them under the OPPS through assignment to New Technology APCs. At least three of the HCPCS codes proposed for reclassification do not meet CMS' own definition of a stand-alone algorithmic analysis of previously generated data.

CMS states that certain of these analyses are currently treated as clinical diagnostic laboratory tests (CDLTs) and paid under the CLFS, but the agency no longer believes that framework is appropriate. CMS' stated rationales for the SaMS proposed framework are: (1) the secondary algorithmic analyses purportedly do not require laboratory services or CLIA-regulated entities to perform them, and an entity performing only algorithmic analyses of previously generated data "may not qualify" as a laboratory under 42 C.F.R. § 493.2; (2) the lack of transparent cost data for proprietary algorithmic components makes crosswalking based on laboratory methodologies inappropriate; (3) the CLFS, unlike the OPPS and PFS, does not include beneficiary cost-sharing or budget neutrality adjustments; and (4) CMS wishes to treat all algorithmic analyses consistently, whether performed on imaging data or on data generated from a laboratory test. On that reasoning, CMS takes the position that these analyses are "other diagnostic tests," rather than "diagnostic laboratory tests," under section 1861(s)(3) of the Social Security Act.

PMC believes the tests that CMS proposes to reclassify under the SaMS framework are CDLTs under current law and present practice. The tests on the proposed list are furnished to Medicare beneficiaries today by laboratories certified under CLIA. They represent important advances in personalized medicine: tests that tell a newly diagnosed cancer patient whether a tumor is likely to recur, whether chemotherapy or androgen deprivation therapy can safely be spared, and which targeted drug therapy will work most effectively with a patient's specific tumor type. Many were developed in clinical laboratories, validated under CLIA quality systems, and are included in nationally recognized practice guidelines. The supposition of the proposed SaMS framework – that an unregulated entity far removed from any laboratory is performing these analyses with nothing but a computer – does not describe the current market for these services.

CMS recently issued a Request for Information on the CLIA regulations (CMS-3485-NC), and its comment period extends beyond the deadline for the OPPS proposed rule. Several questions posed in the CLIA RFI bear

directly on the laboratory SaMS proposals. It would be premature to finalize a payment policy prefaced on the notion that these tests need not be performed be a CLIA-certified laboratory before CMS has considered feedback from stakeholders and resolved relevant questions in the CLIA RFI.

Furthermore, moving these services off the CLFS creates a billing gap that threatens patient access and may increase patient costs. The OPPS payment system is not designed for laboratory services referred to an independent laboratory since OPPS payment is only available to Medicare-enrolled hospital outpatient departments. If finalized as proposed, laboratories that perform analyses may have no clear way to bill Medicare directly for their own work. This could force labs into indirect arrangements where hospitals bill for services they did not actually perform, which undermines, rather than improves, CMS' program integrity goals. When hospitals, physician offices, and laboratories cannot determine how tests may be furnished and billed, some will stop offering the tests, which will limit patient access. In its rationale for the SaMS proposed framework CMS also cites the CLFS's lack of beneficiary cost-sharing as a reason to move to OPPS, but cost-sharing does not ensure appropriate use, actually it shifts costs onto patients, which could discourage them from getting medically necessary tests. For beneficiaries in the middle of cancer treatment decisions, higher costs at precisely the moment they can least afford hesitation could delay or deter access to guideline-recommended diagnostics. At a minimum, any proposal that CMS finalizes should maintain a mechanism for the performing laboratory to bill Medicare directly for the services they provide.

CMS has not addressed any of the operational complexity of implementing the proposed policy. **PMC urges CMS not to finalize the laboratory SaMS policy in CY 2027. CMS should retain these services on the CLFS while the agency further engages stakeholders on a clear, coherent, and sustainable framework for these services across Medicare's payment systems.**

Conclusion

Thank you for considering PMC's response to the CY 2027 OPPS Proposed Rule. We appreciate your commitment to ensuring that beneficiaries have access to transformative treatments and technologies. We look forward to working with you and your colleagues at CMS on policies that enable the availability of personalized medicine across care settings. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] Centers for Medicare & Medicaid Services. Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program Proposed Rule for Calendar Year 2027 (CMS-1850-P). July 7, 2026. ttps://www.federalregister.gov/documents/2026/07/07/2026-13656/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment (accessed August 24, 2026).

[ii] Personalized Medicine Coalition. Comment Letter on Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective

Payment System and Policy Changes and Fiscal Year 2025 Rates, etc. (CMS-1808-P). June 10, 2024. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/06/comment-letter.pdf. (accessed August 24, 2026).

[iii] May, Brandon. "Hospital-Based Outpatient Approach to CAR T Therapy Is Safe, Feasible in Lymphoma and Multiple Myeloma." ASCO Annual Meeting 2023. ASCO Daily News. May 25, 2023. https://dailynews.ascopubs.org/do/hospital-based-outpatient-approach-car-t-therapy-safe-feasible-lymphoma-and-multiple (accessed September 10, 2025).

[iv] Personalized Medicine Coalition. Comment Letter to Centers for Medicare & Medicaid Services on Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency (CMS-1834-P). September 15, 2025. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2025/09/PMC-OPPS-CY2026-Comment-FINAL-09152025.pdf (accessed August 24, 2026).

[v] U.S. Food and Drug Administration. Breakthrough Device Marketing Authorizations as of March 2026. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program (accessed August 24, 2026).

[vi] Personalized Medicine Coalition. Comment Letter to White House Office of Science and Technology Policy on Request for Information on the Development of an Artificial Intelligence (AI) Action Plan. March 14, 2025. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/11/PMC-Comment-Letter-OSTP-RFI-AI-ActionPlan-FINAL.pdf (accessed August 24, 2026).