September 14, 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 and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program (CMS-1848-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 Calendar Year (CY) 2027 Physician Fee Schedule proposed rule.[i] While PMC recognizes there are numerous important payment issues addressed in proposed rule, our comments focus on CMS' proposed Quality Payment Program (QPP) reporting and data submission modifications impacting access to cancer screening tests, the importance of providing expanded coverage and access to biomarker testing that enables early detection of Alzheimer's Disease and Alzheimer's Disease Related Dementias (AD/ADRD), and coding improvements that reimburse clinicians for patient consultations on clinical trial participation. We also offer responses to CMS' request for information on solutions to address unnecessary duplicative testing, the proposal for Software as a Medical Service (SaMS) performed on laboratory test data, and alternatives to the Common Procedural Terminology (CPT) coding system.

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 CMS on the Medicare CY 2027 PFS 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.

Modifying Quality Payment Program (QPP) Reporting and Data Submission to Incorporate Cancer Screening Tests

Personalized medicines have now accounted for at least a quarter of new drug approvals for each of the last ten years, including many in oncology.[ii] Biomarker tests that play a critical role in helping patients evaluate their treatment options are increasingly being incorporated into clinical guidelines for cancer. Timely treatment targeting biomarkers in a patient's tumor can offer better health outcomes than nontargeted drug therapy, such as chemotherapy.[iii] Even though personalized medicine approaches for testing and targeted treatment have been included in updated clinical guidelines for cancer, patient access to personalized medicine remains varied because of clinical practice gaps.[iv] Updated policies, clinical practice reforms, and strategies are needed to encourage the effective implementation of personalized medicine. In response to the CY 2024, CY 2025, and CY 2026 PFS proposed rules, PMC advocated for CMS' inclusion of quality measures that prioritize the role of diagnostics in directing patients to treatments from which they are most likely to benefit and helping to identify genetic risk factors contributing to a patient's conditions. We thank CMS for its ongoing work to incentivize appropriate use of testing in cancer care and to help close implementation gaps impacting patients' access to personalized medicine.

Cancer screening and earlier detection are pivotal to guiding interventions earlier in asymptomatic cancer patients, often resulting in improved outcomes and reduced morbidities associated with advanced cancer as well as potential significant reductions in the cost and complexity of cancer care. PMC appreciates CMS' focus on screening for various cancers, particularly colorectal cancer (CRC), which is the second leading cause of cancer deaths in the U.S.[v] Research has estimated that over 75 percent of CRC-related deaths occur in individuals who are not up to date with screening.[vi] **The CY 2027 PFS proposed rule includes several changes to quality measures used to assess clinician performance in the Medicare QPP. The proposal would modify an existing measure that captures whether patients received CRC screening. PMC is concerned that as currently drafted the proposal fails to capture the use of newly approved, Medicare covered tests that could facilitate expanded CRC screening.**

CMS seeks to revise the numerator definition for Submission Criteria 4 (colorectal cancer screening) of Quality Measure #497, Preventive Care and Wellness (Composite). To meet the quality action, CMS is proposing that a clinician must document in the medical record review of the CRC screening report, including a report the patient provides during the visit. This aligns with changes made to Quality Measure #113 in the CY 2026 Physician Fee Schedule Final Rule. PMC supports this proposed change because it encourages standardization of documentation practices across clinical settings, promoting care coordination and appropriate patient follow-up, if needed. However, despite CMS's desire to enhance the impact of this quality measure to ensure that clinically appropriate information is being transmitted to and reviewed by health care teams, as currently drafted, the quality measure does not recognize the use of every guideline-evaluated, FDA-approved, Medicare-covered screening option. A clinician who reviews and documents a test not yet included on the list of "appropriate screenings" would not receive quality credit because Submission Criteria 4 relies on the same

definition of "appropriate colorectal cancer screening" used in the standalone CRC screening measure, Quality Measure #113. Quality Measure #113 recognizes the importance of early detection and prevention by allowing health care providers to report the percentage of patients ages 45-75 who received appropriate CRC screening but the measure does not include all FDA-approved and Medicare-covered tests in its list of "appropriate screenings" because it is based on U.S. Preventive Services Task Force (USPSTF) recommendations from five years ago, before these tests were FDA approved and covered by CMS. **Because the USPSTF has not updated its CRC recommendations, a provider operating under guidelines who offers and whose patient completes a test not yet on the list of "appropriate screenings" cannot report it as part of the QPP. CMS should work to modify its CRC screening quality measures so that they align with CMS coverage and clinical practice guidelines and do not pose a significant disincentive to appropriately using non-invasive testing that addresses CRC screening gaps.**

Improving Early Detection of Alzheimer's Disease/Alzheimer's Disease Related Dementias (AD/ADRD) through Biomarker Testing

As part of the CY 2027 PFS proposed rule CMS asks stakeholders for their input on the role of biomarker diagnostic testing for AD/ADRD. While this request for information focuses primarily on lifestyle interventions, it provides an opportunity for CMS to take transformative steps now to ensure the U.S. can address immediate and future needs posed by AD/ADRD. The U.S. population is aging rapidly – currently, there are 58 million individuals aged 65 and older and this number is projected to rise to 82 million by 2050. Age is the greatest risk factor for AD/ADRD. One in three older adults die with Alzheimer's or another dementia. It kills more than breast cancer and prostate cancer combined.[vii]

Recent estimates suggest that approximately 22 percent of individuals aged 65 and older have mild cognitive impairment (MCI), often considered a precursor to dementia, and up to 10 percent have dementia.[viii] As our nation's aging population grows, the number of Medicare beneficiaries with MCI or dementia is expected to increase exponentially. In addition to individuals over the age of 65, an estimated 200,000 Americans under 65 years old are living with younger-onset dementia and may qualify for Medicare coverage. Intervention well before symptom manifestation provides the best chance for protecting brain health and improving quality of life for individuals and families living with or at risk for AD/ADRD.

Science has shown that biological changes associated with AD/ADRD begin in the brain 15-20 years before clinically apparent cognitive symptoms. Delaying action until symptoms emerge means missing decades during which risk reduction strategies and potentially disease-modifying therapies could have their greatest opportunity to prevent, delay, or alter AD/ADRD progression. Blood-based biomarkers (BBMs), like those measuring plasma p-tau217, offer minimally invasive, cost-effective tools for earlier detection. BBMs may make efforts to treat earlier and monitor disease progression more accessible and practical. BBMs may also help improve overall outcomes for individuals living with cognitive impairment, especially those in the very early stages of disease when current interventions may be most effective. In our response to the CY 2026 PFS proposed rule, PMC supported CMS' Improvement Activity to encourage clinicians in primary care to better assess and address a person's memory concerns over time and asked for consideration of BBMs as they became available.[ix] **PMC further urges CMS to pursue a broad approach to incentivizing early detection of AD/ADRD through expanded coverage and access to validated BBMs as well as other established fluid and imaging biomarker tests.**

Reimbursing Clinicians for Patient Clinical Trial Consultations

The CY 2027 proposed rule proposes the possible creation of a Healthcare Common Procedure Coding System (HCPCS) billing code to reimburse clinicians for consulting patients about clinical trial participation. A key bottleneck for clinical trials in the U.S. is recruiting a sufficient patient population to provide confidence in the

results. Low patient recruitment is the most common reason for early termination of oncology, cardiovascular, and AD clinical trials. Only 1 percent of eligible AD patients and 8 percent of adult patients with cancer participate in clinical trials. Improving trial enrollment rates could accelerate the pace of advances, expand patient access to novel treatment options, and maximize the return on public and private R&D investments, particularly in therapeutic areas where personalized medicine approaches are increasing. **PMC agrees with CMS that a billing code would incentivize more clinicians to engage with their patients on trial participation and we encourage CMS to develop a HCPCS code to reimburse clinicians for discussions about clinical trials.**

CMS is also seeking input on the appropriate duration of clinical trial patient consultations and eligibility for non-physician qualified healthcare professionals to seek reimbursement through this proposal. Some patient situations may be simple, such as consulting about screening trials for a healthy patient with a family history that increases risks for a chronic disease. In these situations, 10 minutes may be an appropriate duration. Some patient situations may be more complex, such as patients with a newly diagnosed serious disease that has numerous trial options available, all conducted at different locations and entailing distinct treatment modalities. For more complex situations such as these, 30 minutes or more may be appropriate. **Reimbursing for a 20-minute consultation may not be sufficient in complex situations and should be reconsidered by CMS when finalizing the proposal.** Furthermore, under current practices, Registered Nurse (RN) clinical trial coordinators and other advanced practice providers often conduct clinical trial consultations in person or via telehealth without reimbursement. **PMC requests that CMS allow physicians, RNs, and advanced practice providers to bill for in-person or telehealth clinical trial consultations.**

Informing Solutions to Reduce Unnecessary Duplicative Testing

PMC shares CMS' goal of reducing genuinely unnecessary testing as it harms patients, wastes resources, and undermines trust in the system. However, we are concerned by the approach CMS is considering in the CY 2027 PFS proposed rule because it could have unintended consequences for clinical laboratories who provide services in good faith and negatively impact patient access to clinically appropriate testing. We do not believe this is CMS' intent. In practice, clinicians order tests in the care of their patients, laboratories perform them in response to those orders and do not have access to the patient's full medical record, claims history, or prior results held by other providers or laboratories. A laboratory frequently receives only the test order and patient's specimen. The laboratory has no way of knowing another provider recently ordered the same test. Penalizing laboratories through non-payment or recoupment for providing services for the same test would misdirect enforcement at the party least able to prevent the problem. Unfortunately, ordering providers also often lack timely, usable access to prior test results at the moment they place an order. **CMS should ensure that ordering clinicians have the tools to see relevant prior test results at the point of order before imposing any payment changes under this section of the CY 2027 PFS proposed rule.**

Furthermore, not all repeat testing is duplicative. Serial and repeat testing in personalized medicine increasingly relies on the utilization of a patient's unique molecular, genetic, or biomarker profile over time to guide targeted treatment, monitor resistance, and evaluate disease progression. Because a test shares a code with a prior test or it addresses the same condition, it should not automatically be considered unnecessary or duplicative. There is also no single interval after which a test is automatically duplicative as some tests are appropriately repeated several times a year, others only once in a lifetime. **CMS should clearly distinguish avoidable duplication of testing from clinically appropriate repeat, serial, or complementary testing that supports personalized medicine. In order to align changes to payment policy with scientific advances that improve care for Medicare beneficiaries, any frequency limits on tests considered by CMS going forward must be evidence-based and set prospectively on a test-specific basis through the established coverage (NCD/LCD) process with flexibility for ordering providers to use attestations or modifiers (e.g., disease**

progression, therapy monitoring, changed clinical status) to justify medically necessary testing above any limit.

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. 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.[x] In the CY 2026 PFS proposed rule CMS acknowledged that innovative software applications and AI-based tools are not well accounted for in CMS' current payment structure and that 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. CMS proposes to formally recognize Software as a Medical Service (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. **PMC supports CMS' goal of establishing a pathway for algorithm-only laboratory services; however, we have concerns with elements of CMS's proposal that must be addressed to ensure broad patient access and adequate payment for these technologies.**

In the CY 2027 PFS proposed rule, CMS proposes to treat algorithm-only laboratory tests like other SaMS furnished on non-laboratory data, removing them from the Clinical Laboratory Fee Schedule (CLFS) and instead paying for these services under the PFS. CMS' proposal presumes a clear separation between data generation and algorithmic analysis, but in practice, these activities are inextricably linked clinically and operationally with the underlying wet laboratory procedure. 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. The overall approach proposed by CMS to treat algorithm-only laboratory tests like other SaMS furnished on non-laboratory data does not reflect the nature of these tests when they are furnished by a CLIA-certified laboratory. **When validated and offered by a CLIA-certified laboratory, complete with clinician orders and laboratory director signoffs, these analyses function as clinical diagnostic laboratory tests (CDLTs) and should remain on the CLFS.**

Similar to PMC's comments on CMS' CY 2027 OPPS SaMS proposal, we believe moving these services off the CLFS would create a billing gap that threatens patient access to personalized medicine. Clinical laboratories cannot bill the PFS directly for "other diagnostic services," the benefit category in which CMS is proposing to reclassify SaMS analyses performed on laboratory tests. If finalized as proposed, laboratories that perform analyses may have no clear way to bill Medicare directly for their own work. Performing laboratories would be required to contract with other Medicare-enrolled providers (such as physician practices or hospitals), forcing those outside entities to bill for services they did not actually furnish. This type of indirect arrangement would cause confusion over how tests may be furnished and billed. As a result, some laboratories may stop offering these types of tests, which will limit patient access. The CLFS also does not impose Medicare beneficiary cost-sharing, but cost-sharing would apply at 20 percent under the PFS. The presence or absence of cost-sharing does not determine whether a service is medically necessary or appropriately billed; however, shifting these tests to a payment system with beneficiary cost-sharing would risk further deterring patients from accessing medically

necessary testing. Furthermore, the proposal to contractor price algorithm-only services under the PFS would decrease transparency rather than enhance it and may further limit patient access. The contractor pricing process is unpredictable, opaque, and can result in wide payment rate variability across geographies. **PMC strongly urges CMS to retain algorithm-only laboratory services on the CLFS. At a minimum, any proposal that CMS finalizes should use existing CLFS payment rate data to set PFS payment that closely approximates the current CLFS payment rate and maintains a mechanism for performing laboratories to bill Medicare directly for the services they provide.**

PMC believes the tests that CMS proposes to reclassify under the SaMS framework are CDLTs under current law and present practice. 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. 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. This stakeholder engagement should include resolution to open questions generated by CMS' recent request for information regarding what activities data-only facilities perform to generate, or help to generate, test results and interpretations and whether they require CLIA certification. We also feel that continued work towards a standardized definitional framework for SaMS is required to clarify the types of services eligible for payment under a future pathway.**

Meaningfully Improving the Current Procedural Terminology (CPT) Coding System While Studying Potential Alternatives

Through the proposed CY2027 PFS rule CMS is seeking information on potential alternatives to the Current Procedural Terminology (CPT) coding system, including ICD-10-based coding. Coding is foundational to third party payer reimbursement by both public and private payers. It provides the key inputs for pricing, payment, and coverage decisions, so the process must be clear, transparent, and predictable, with meaningful opportunity for public input.

The American Medical Association (AMA) currently manages tens of thousands of codes backed by decades of guidance and institutional knowledge. Since the adoption of the CPT code set as a mandatory HIPAA transaction standard in the early 2000's, extensive integration of CPT coding has occurred throughout virtually every aspect of modern health care for the laboratory and other professional services it covers.

However, over the past two and a half decades, several negative aspects of the adoption of CPT as the mandatory code set for laboratory and other professional services have become apparent, which warrant CMS's consideration of potential alternatives. CPT is a proprietary code set copyrighted by the AMA for which royalties are charged for its use. Laboratories and other professional service providers have no alternative but to use CPT to obtain third party reimbursement, and there is no limit to how much AMA can charge for the use of its legally mandated code set, resulting in what amounts to an unregulated monopoly. Further, the AMA controls the establishment of and changes to CPT codes through a private CPT Editorial Panel in which adequate laboratory representation is not assured. The CPT process also involves confidentiality requirements that shield the decision-making process from appropriate public scrutiny. The code set itself is relatively unstructured, without a comprehensive glossary for core terminology, code characters generally have no specific meaning, and the code set has limited space for new procedures and additional specificity.

ICD-10-PCS is sometimes discussed as a potential alternative to CPT because it is in the public domain and does not involve copyright restrictions or licensing considerations. In addition, an alternative code structure

could theoretically provide more opportunities to accommodate future innovations in personalized medicine. However, these potential advantages could only be achieved by overcoming the significant challenges associated with implementation. For example, ICD-10-PCS currently does not contain a laboratory services section capable of supporting the breadth and complexity of modern laboratory testing. Such a framework would need to be developed from the ground up through extensive collaboration among CMS, laboratories, health care providers, payers, health information technology vendors, and other stakeholders. There would be no existing laboratory code set that directly maps to current CPT-based payment systems, creating significant challenges for Medicare rate setting, claims processing, coverage policies, utilization management programs, quality measurement programs, and private payer reimbursement methodologies.

During any transition period, laboratories and other stakeholders could be required to support both coding systems simultaneously. Maintaining dual systems would impose significant operational and financial burdens, increase the risk of payment disruption, and create uncertainty throughout the health care marketplace. In addition, extensive regulatory revisions, systems modifications, policy remapping exercises, and stakeholder education efforts would be required before a new coding system could be fully operational. The industry faced these same kinds of challenges through the adoption of HIPAA's current transactions and code set standards, such as the transition from ICD-9-CM to ICD-10-CM.

Given the scope of these challenges, PMC believes that transitioning from the current CPT framework to a new coding system likely would require a decade or more of planning, development, testing, implementation, and adoption. A transition period of approximately 10 to 12 years would not be unreasonable given the breadth of infrastructure, payment methodologies, and coverage policies that would need to be redesigned and validated.

PMC recommends that CMS undertake a comprehensive, multi-stakeholder study evaluating the options for, and the positive and negative implications of, moving laboratory and other professional services to a different procedural coding framework. Such a study should include laboratories, providers, payers, standards organizations, health information technology vendors, patient representatives, and government agencies. A thorough evaluation would better position regulators and stakeholders to assess whether an alternative coding framework could achieve benefits that outweigh the challenges associated with replacing the current national coding standard.

While such a study is pending, there is room for improvement in AMA's processes for CPT code establishment and maintenance, including greater applicant engagement when proposed descriptors require modification, increased consistency and transparency in code creation and descriptor development, meaningful stakeholder input on policy and application changes, greater transparency regarding advisory group membership and confidentiality protections, and broader representation from stakeholders involved in clinical diagnostics (i.e., independent clinical laboratories, geneticists, patient representatives, associations representing the latest advancements in technology, and Medicare program experts). Collectively, these improvements would enhance transparency, consistency, stakeholder confidence, and collaboration while supporting the development of coding infrastructure for innovative diagnostic and other professional services essential to personalized medicine. **PMC therefore recommends that CMS work with the AMA and other stakeholders to make meaningful improvements to the existing CPT coding system while it is studying potential alternatives to the CPT code set.**

Conclusion

Thank you for considering PMC's response to the CY 2027 PFS 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

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[i] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program (CMS-1848-P). July 16, 2026. https://www.govinfo.gov/content/pkg/FR-2026-07-16/pdf/2026-14327.pdf
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