March 30, 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: Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) Request for Information (RFI) [CMS-6098-NC]**

Dear Administrator Oz:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising nearly 200 institutions from across the health care spectrum, appreciates the opportunity to comment on the Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) Request for Information (RFI).[i] PMC supports CMS' goal of reducing inappropriate Medicare payments and stopping entities responsible for fraud in federal health care programs. However, we are concerned that some components of the RFI focused on laboratory testing do not distinguish fraudulent entities who break the law from established laboratories that provide medically appropriate testing ordered by a clinician. Furthermore, we believe the RFI incorrectly implies that high costs and increased utilization of genetic and molecular diagnostic tests may be attributable to fraud. Over the past decade, scientific and technological advances have vastly expanded the tools available to physicians for screening, diagnosing, treating, and monitoring patients based on their individual circumstances and biological characteristics.[ii] These tools include genetic and molecular testing that are the foundation of personalized medicine and are increasingly becoming standard of care. We strongly urge CMS to protect timely patient access to medically appropriate testing in any changes the agency considers to Medicare program integrity, claims submission, and fraud prevention related to laboratory tests.

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.

**Statement of Neutrality**

Many of PMC's members will present their own responses to the Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) Request for Information (RFI).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 CRUSH RFI.

***The Role and Growth of Genetic and Molecular Testing in Personalized Medicine***

Precision diagnostics are the foundation of personalized medicine which is helping to shift patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions. Because of advances in diagnostic testing, providers often have a fuller understanding of the relationship between a patient's genetic makeup and other molecular drivers of disease and how those factors influence treatment effectiveness. As diagnostic testing has been integrated into standard of care, more clinicians have the information necessary to guide patients in their healthcare decision making toward treatments that are likely to benefit them and away from those that could cause harm.

Technological and scientific advancements in genetic and molecular testing, in particular, have demonstrated value in patient care by allowing for screening and detection of many early-stage cancers, enabling the prediction of treatment response and risk stratification for potential relapse across certain cancers, supporting the diagnosis of rare diseases and informing treatment where interventions exist, and more recently ruling out Alzheimer's disease as the cause of a patient's cognitive symptoms in the primary care setting.

Approaches to care incorporating genetic and molecular diagnostic testing are recommended by guideline bodies including the National Comprehensive Cancer Network (NCCN),[iii] the U.S Preventative Services Task Force (USPSTF),[iv] and the American Society for Clinical Oncology (ASCO).[v] These guidelines are informing clinical care for individuals with non-small cell lung cancer, colorectal cancer, prostate cancer, breast cancer and a growing number of hematological cancers. Medicare has even recognized the necessity of leveraging genetic testing to provide high quality care through its national coverage of next-generation sequencing for Medicare beneficiaries with advanced cancer.[vi]

The CRUSH RFI cites a report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG) on Medicare Part B spending for clinical diagnostic laboratory tests. According to the OIG report, overall spending on laboratory testing was $8.4 billion in 2024, a 5 percent increase from 2023, and it noted the increased use of genetic tests.[vii] The report does not reach conclusions about legitimacy of claims for genetic tests or laboratories submitting them. The CRUSH RFI proceeds to reference fraud cases related to illegitimate entities responsible for defrauding Medicare through ordering medically unnecessary urine tests and other tests whose results were never provided to patients or their physicians. The OIG report and CRUSH RFI do not recognize that a driver of increased spending on genetic testing may be attributed to broader applications for testing in diseases affecting the Medicare population and growing acceptance of genetic and molecular testing by providers and patients as a standard of care.

Higher utilization and increased spending on laboratory testing services do not constitute fraud on their own. Likewise, genetic tests and the laboratories that perform them should not be considered inherently suspect. Innovative genetic and other molecular diagnostic tests provide real value to the Medicare program by allowing for evidence-based care that often avoids costly and ineffective treatments. **PMC supports the use of program integrity tools to address fraud, waste, and abuse in molecular diagnostic testing. However, as CMS considers any new ways or enhanced mechanisms to conduct these activities in the Medicare program, it is important for the agency**

**to take a targeted data-driven and risk-based approach that differentiates fraudulent actors that submit false claims from reputable laboratories that perform medically appropriate testing ordered by clinicians to help improve patient outcomes, reduce unnecessary treatment costs, and lead to better patient and provider satisfaction with health care experiences.**

***Balancing Patient Access to Appropriate Diagnostic Testing and Fraud Prevention***

Personalized medicine depends on the consideration of a patient's molecular and biological characteristics and also on their values and clinical circumstances. Access to appropriate therapy based on this type of individualized clinical decision making relies on timely access to diagnostic tests, including laboratory genetic and molecular tests referenced in the CRUSH RFI. In order to fully benefit from personalized medicine, however, patients must have access to the appropriate diagnostic tests from the beginning of their diagnosis and treatment journey.

Some approaches explored by CMS in the RFI such as requiring laboratory registration in the DEX Diagnostics Exchange Registry, expanding the authority of Medicare Advantage (MA) organizations to suspend payments to providers, and shortening the deadline for laboratory claim submission are not likely to be useful for fighting fraud, waste, or abuse. We believe these approaches may impede legitimate laboratories' ability to provide patient access to diagnostics as they would need to increase the time, effort, and resources spent responding to medical records requests and other inquiries for coverage and reimbursement of clinically appropriate testing. A laboratory or hospital can register in the DEX Diagnostics Exchange Registry with basic information, but the registry is not a tool that would curb fraud.

CMS suggests in the RFI that shortening Medicare Part A and Part B statutory claims deadline could reduce waste fraud and abuse. There are circumstances that should be considered where information required to file claims are not available to laboratories, such as those where laboratories receive patient specimens and test orders from a physician separately, instances when payors have not yet updated new codes into their claims processing systems, or when a test is still undergoing MolDX technical assessment and laboratories must hold claim submission for up to 12 months for completion. **We do not believe that the claims submission deadline for Medicare Parts A and Part B claims should be shortened because some legitimate laboratories furnishing medically necessary services to patients would not have a way to receive payment.**

Finally, protecting the Medicare program and its beneficiaries from unnecessary spending and potential fraud is important, but not before promoting patient access to high-quality, appropriate care. The cases included in the CRUSH RFI demonstrate that the tools already in place work to catch bad actors fraudulently ordering tests.[viii] Additional resources from Congress could bolster Medicare's efforts to distinguish between fraudulent and legitimate test ordering. In the RFI CMS states that it lacks explicit authority to direct Medicare Advantage (MA) organizations and Medicare Part D plan sponsors to suspend payments to providers and suppliers that operate exclusively in Medicare Part C or Part D. Utilization management tools, including prior authorization employed by MA organization, can restrict patient access to services and delay or deny payment to legitimate providers. MA organizations sometimes deny medically necessary biomarker testing that is explicitly covered under national coverage determinations and local coverage determinations. Advanced cancer patients in particular do not have time to wait while these issues are resolved as every day the patient may not on the right treatment for them. Additional authority for MA organizations to suspend payments would exacerbate these problems and further disrupt reimbursement and patient access without improving program

integrity. **CMS should leverage its existing program integrity tools to prevent fraud, waste, and abuse and should not give MA organizations the authority to suspend provider payments.**

**Conclusion**

Thank you for considering these comments. We look forward to serving as a resource to you and your colleagues on paths that ensure sustainability of the Medicare program but maintain an ecosystem for innovation and patient access to personalized medicine. If you have any questions about the contents 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 and Medicaid Services. *Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) Request for Information (RFI). [Docket No. 2026–03968].* February 27, 2026. https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23705.pdf (accessed March 24, 2026).

[ii] Agarwal A, Pritchard D**,** et al. *"*A Quantitative Framework for Measuring Personalized Medicine Integration into US Healthcare Delivery Organizations." *Journal of Personalized Medicine*. 2021. https://www.mdpi.com/2075-4426/11/3/196/htm. (accessed March 24, 2026).

[iii] National Comprehensive Cancer Network. Category 1 https://www.nccn.org/guidelines/category_1 and Category 2 Guidelines for cancer treatment, detection, prevention and risk reduction https://www.nccn.org/guidelines/category_2 (accessed March 24, 2026).

[iv] U.S. Preventive Services Task Force A and B Recommendations. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations (accessed March 24, 2026).

[v] American Society for Clinical Oncology (ASCO) Clinical Practice Guidelines https://ascopubs.org/guidelines (accessed March 24, 2026).

[vi] Centers for Medicare and Medicaid Services. *National Coverage Determination for Next Generation Sequencing in Advanced Cancer*. NCD 90.2. January 27, 2020. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=372 (accessed March 24, 2026).

[vii] Health and Human Services Office of Inspector General, *Total Medicare Part B Spending on Lab Tests Rose in 2024, Driven by Increased Spending on Genetic Tests; OEI-09-25-00330* January 23, 2026. https://oig.hhs.gov/reports/all/2026/total-medicare-part-b-spending-on-lab-tests-rose-in-2024- driven-by-increased-spending-on-genetic-tests/ (accessed March 24, 2026).

[viii] U.S. Department of Health and Human Services. Office of the Inspector General Fraud Alert: Genetic Testing Scam. September 27, 2019. *https://oig.hhs.gov/fraud/consumer-alerts/fraud-alert-genetic-testing-scam/. Lab Operator Convicted of $4M Medicare Fraud Scheme. February 25, 2025. https://oig.hhs.gov/fraud/enforcement/lab-operator-convicted-of-4m-medicare-fraud-scheme/. Department of Justice. Federal Law Enforcement Action Involving Fraudulent Genetic Testing Results in Charges Against 35 Individuals Responsible for Over $2.1 Billion in Losses in One of the Largest Health Care Fraud Schemes Ever Charged. September 27, 2019. https://www.justice.gov/archives/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against. (accessed March 24, 2026)*