



March 30, 2026

Dr. Mehmet Oz, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6098-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted electronically to: <http://www.regulations.gov>

Re: Request for Information (RFI) Related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH)

Dear Administrator Oz:

The College of American Pathologists (CAP) appreciates the opportunity to comment on ways to make the Centers for Medicare & Medicaid Services (CMS) “more effective in crushing fraud.” Protecting Medicare beneficiaries and taxpayer dollars is essential. We share this Administration’s commitment to combating fraud and abuse, and strongly support targeted enforcement efforts, including those directed at inappropriate self-referral schemes, kickback arrangements, and testing without individualized medical necessity. **At the same time, increased utilization or spending alone does not establish systemic fraud, and it is important that regulatory responses do not unintentionally conflate specific bad actors with compliant laboratories operating within coverage policies and clinical guidelines.**

We respectfully ask CMS to ensure any policy responses distinguish between documented fraud schemes and the broader field of molecular diagnostics, which has become an integral part of modern evidence-based care. Policies that broadly apply additional administrative requirements to all laboratories risk penalizing compliant providers while failing to target those intentionally engaging in fraudulent conduct. **We also urge CMS to reevaluate its use of the Molecular Diagnostic Services Program (MoIDX Program).** We see substantial challenges with the MoIDX program as it exists today and believe any expansion of the program would represent a significant structural shift in Medicare coverage administration, raising operational and policy considerations while potentially limiting patient access to innovative diagnostics, particularly in rural and underserved markets. Further, it is our position that the MoIDX Program has not reduced fraud, waste and abuse related to laboratory testing, and instead, **we respectfully recommend consideration of more targeted approaches and strengthening/reinforcing anti-fraud mechanisms already in place.**

Reducing Medicare Fraud Related to Laboratory Tests

In this RFI, CMS states it is concerned about fraud, waste, and abuse related to laboratory tests and has targeted this as a focus area, specifically highlighting “genetic tests and molecular diagnostic tests.” CMS

highlights a January 2026 Department of Health and Human Services (HHS) Office of the Inspector General (OIG) report that provides a descriptive snapshot of utilization and spending trends under the Clinical Laboratory Fee Schedule (CLFS). The report – and CMS – note that although “genetic tests represented only 5 percent of lab tests paid under Part B in 2024, they accounted for 43 percent (\$3.6 billion) of Part B lab spending.” **However, spending data alone does not establish improper utilization or systemic program failure** – this difference in percentage of tests and spending primarily reflect the fundamental differences in technological complexity, bioinformatics requirements, clinical interpretation demands, and capital equipment investment. Molecular and genetic tests frequently involve expensive next-generation sequencing platforms, highly trained personnel, and individualized precision analyses. By contrast, many of the other laboratory tests in more common usage are based on technology and equipment that is well established and lower in price, as a result. **A higher cost, smaller share of tests can therefore reasonably translate into a larger share of spending.**

Further, while genetic and molecular test costs may be higher, the appropriate test at the right time often reduces downstream costs. For example, appropriate, timely testing can help a patient avoid ineffective, broad-based chemotherapy, reduce adverse drug reactions, prevent hospitalizations, and support precision medicine treatment decisions. Genetic and molecular tests can also advance preventive care by identifying individuals at higher risk for certain conditions and supporting lifestyle changes to reduce the chance of developing disease. Molecular and genetic testing provide more precise individualized patient care, earlier and more accurate diagnoses, improved treatment selection, the avoidance of trial-and-error prescribing, and harmful treatments. It enhances diagnosis, individualizes therapy, reduces unnecessary lengthy treatments, and enables proactive, risk-based care.

This success of precision medicine treatment decisions and targeted therapies has given rise to new molecular pathology services. The number of Category I molecular pathology CPT codes increased from 120 in 2015 to 292 in 2022 and 307 in 2025. Similarly, multianalyte assays with algorithmic analyses (MAAA) and proprietary laboratory analyses (PLA) codes grew from just 19 in 2015 to 300 in 2022 and 492 in 2025. This expansion reflects both technological advances and increasing clinical adoption. Many of these new services can reasonably be attributed to molecular testing for cancer treatment and targeted therapies that are dependent on the presence of tumor specific mutations to be effective (i.e., personalized medicine).

As precision medicine expands, molecular diagnostics appropriately represent a growing share of laboratory expenditures, supported by the rigorous clinical evidence of guidelines. Genetic and molecular testing are incorporated in the CAP’s clinical practice guidelines and clinical practice guidelines from organizations such as the National Comprehensive Cancer Network, American College of Medical Genetics and Genomics, Association for Molecular Pathology, American Society of Clinical Oncology (ASCO), American College of Obstetricians and Gynecologists, National Institutes of Health, the World Health Organization, and numerous more. A growing body of multi-society authored, evidence-based guidelines now recommend molecular testing of malignant tumors to inform the selection of targeted therapies. The CAP, for example, has published evidence-based guidelines supporting techniques such as microdissection for certain molecular studies, including analyses of lung cancers to guide EGFR- and ALK-directed treatments. Additionally, organizations including the CAP, ASCO, and others have



developed clinical quality measures that focus on appropriate use of genetic and molecular testing to prioritize high-value care.

Finally, a factor to consider when reviewing the increase in Medicare spending on molecular and genetic testing is the increase in the number of FDA-approved biomarker-based cancer therapeutics. This increase in precision oncology therapeutics is increasing the importance of genetic and molecular testing for patients with cancer. An analysis of FDA-approved therapeutics from 1998 to 2022 found that 43% of the drugs or biologics (86 of 198) targeted a molecular aspect of the patient's cancer and required pretreatment biomarker testing.¹ Among these 86 precision oncology drugs, 80% (69 of 86) involved a genomic biomarker that required next generation sequencing (NGS) testing. The testing is a necessary precursor to receipt of the therapeutics because the therapies are biomarker-directed with potential for lack of benefit and treatments have high costs. Since the therapies are relevant to many cancer types, many patients with cancer undergo testing. Other studies also point to increases in molecular and genetic testing due to an increasing number of precision medicine therapeutics.^{2,3,4,5}

We also note that molecular diagnostic tests are generally not ordered by pathologists or laboratories, but rather by treating clinicians who are responsible for the overall management of the patient's care. As such, policies that place primary utilization controls, evidentiary burdens, or administrative requirements at the laboratory level may not effectively address the source of inappropriate ordering where it exists. To the extent CMS has concerns regarding medical necessity or utilization patterns, those concerns are more appropriately addressed through provider education, ordering controls, and targeted program integrity efforts focused on ordering practitioners. Aligning oversight mechanisms with the point of clinical decision-making would better ensure program integrity while avoiding unintended consequences for laboratories that are acting in accordance with valid physician orders and would more directly target the source of inappropriate utilization.

Again, we agree that many enforcement actions are necessary and appropriate. However, it is our understanding that the abuses highlighted (for example, those involving CPT 81408) have largely involved a relatively narrow set of actors – telemarketing operations, shell or “pop up” laboratories, a small subset of physicians collaborating with them, and the like. Imposing substantial new administrative burdens on a broad group of compliant providers to address the abuse of a small number of bad actors at the fringe of health care, risks being both inefficient (financial, staffing, and time) and inequitable. Further, overbroad policy reactions risk discouraging innovation, reducing patient access to clinically appropriate testing, and slowing adoption of validated precision medicine tools.

¹ Suehnholz SP, Nissan MH, Zhang H, et al. Quantifying the Expanding Landscape of Clinical Actionability for Patients with Cancer. *Cancer Discovery*. (2024) 14 (1): 49–65. <https://doi.org/10.1158/2159-8290.CD-23-0467>

² Tibau A, Hwang TJ, Molto C, et al. Clinical Value of Molecular Targets and FDA-Approved Genome-Targeted Cancer Therapies. *JAMA Oncol*. 2024;10(5):634–641. doi:10.1001/jamaoncol.2024.0194

³ Groisberg R, Hong DS, Roszik J, et al. Clinical Next-Generation Sequencing for Precision Oncology in Rare Cancers. *Mol Cancer Ther*. 2018 Jul;17(7):1595-1601. doi: 10.1158/1535-7163.MCT-17-1107.

⁴ Meric-Bernstam F, Brusco L, Shaw K, et al. Feasibility of Large-Scale Genomic Testing to Facilitate Enrollment Onto Genomically Matched Clinical Trials. *J Clin Oncol*. 2015 Sep 1;33(25):2753-62. doi: 10.1200/JCO.2014.60.4165.

⁵ Ersek JL, Black LJ, Thompson MA, et al. Implementing Precision Medicine Programs and Clinical Trials in the Community-Based Oncology Practice: Barriers and Best Practices. *Am Soc Clin Oncol Educ Book*. 2018 May 23;38:188-196. doi: 10.1200/EDBK_200633.

MolDX Program Requirements and Challenges

As CMS explains, the MolDX Program, administered by Palmetto GBA on behalf of CMS, was established in 2011 “to determine and streamline coverage and reimbursement for molecular diagnostic tests on behalf of the Medicare program.” However, today Palmetto GBA is marketing its products and services in the molecular diagnostics space beyond the MolDX Program for Medicare. Increasingly, Medicare Advantage plans – such as those operated by UnitedHealthcare, Optum Care, and Humana – have implemented the requirement that molecular pathology claims contain DEX Z-codes, which are proprietary alpha-numeric codes obtained from the Palmetto DEX Registry. UnitedHealthcare has also implemented this requirement in its commercial and Medicaid plans. According to UnitedHealthcare, this helps “determine the exact test that has been performed, facilitating reimbursement determinations.”⁶ Importantly, obtaining a DEX Z-code from Palmetto GBA often involves completion of a Technical Assessment (TA) evaluation – also administered by Palmetto GBA – to determine if a test demonstrates clinical utility and meets analytical and clinical validity criteria. Of note, while MolDX and the DEX Registry are both administered by Palmetto GBA, registration in the MolDX Program is not required to register in DEX and obtain a Z-code.

We do not believe that MolDX registration or the added requirement of a DEX Z-code has materially reduced fraud, waste and abuse related to laboratory testing. Evidence suggests that program integrity vulnerabilities are more directly tied to the presence – or absence – of clear coverage policies and claims edits at the Medicare Administrative Contractor (MAC) level, rather than to the use of Z-codes. For example, the OIG report on CPT 81408 found that two of the seven MACs accounted for 97 percent of the \$888.2 million in at-risk payments; notably, those two MACs lacked Local Coverage Article guidance limiting the use of that code, while the other five MACs had such guidance in place. This variation suggests that targeted implementation of existing claims editing and coverage tools can be highly effective, and that program integrity challenges are more closely tied to gaps in consistent application rather than the absence of additional coding structures.

At the same time, the CAP believes there are significant concerns with the Z-code requirements. Unlike the American Medical Association’s (AMA) Current Procedural Terminology (CPT) processes code set – which is transparently developed with broad stakeholder input, including CMS and other payers who are represented on the CPT Editorial Panel – DEX Z-codes do not provide comparable opportunities for stakeholder input, public review, or independent scrutiny. To obtain a Z-code, laboratories are required to submit detailed information regarding their tests but have little transparency into the criteria used for code assignment, the review methodology, or the decision-making process. In addition, there are limited opportunities for affected parties to comment on or challenge determinations regarding code assignment or how those identifiers are subsequently linked to coverage policies. The absence of a transparent, multi-stakeholder governance structure that allows for appropriate stakeholder feedback raises concerns about accountability, consistency, and fairness, particularly as Z-codes increasingly function as prerequisites for payment and are being adopted by commercial payers outside the Medicare program.

⁶ <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-Molecular-Pathology-Policy-Professional-Facility.pdf>



In contrast to the Z-code process, the AMA's CPT process is open to the public and highly transparent. Anyone can request a new code, attend the meetings three times a year, and contribute to the process of updating the medical terminology. Over 10,000 procedure codes are defined in CPT, which are updated annually (including addition of new codes, deletion of codes that are no longer used, and revisions in procedure descriptions) to ensure that it accurately reflects current medical practice. Further, CPT is a nationally standardized, universally recognized coding system used by Medicare, Medicaid, all commercial insurers, hospitals, laboratories, physicians, and outpatient facilities. It supports portability, research, global interoperability, and multinational product development. It is used and referenced in all billing systems, electronic health record systems, and global health informatics standards, and is the basis for crosswalks to Systematized Nomenclature of Medicine (SNOMED), Logical Observation Identifiers Names and Codes (LOINC), and Systematized Nomenclature of Medicine (ICD) systems. CPT provides uniformity and reduces administrative fragmentation as it is fully integrated into U.S. medical billing infrastructure; every billing system, clearinghouse, and practice management tool in the U.S. recognizes CPT codes by default. CPT provides seamless interoperability, fewer technical barriers, no need for additional registries, portals, or parallel coding processes. It is already embedded in the national payment infrastructure, minimizing administrative burden. It is comprehensive and central to the entire health care system, not just a niche domain. CPT is also used for administrative management purposes such as claims processing and developing guidelines for medical care review.

Further, the CAP considers the Z-code requirement to be duplicative, disruptive, administratively burdensome, and cost prohibitive for many pathologists and laboratories. Laboratories must align CPT codes, Z-codes, coverage policies, and more. Minor discrepancies can lead to denials unrelated to clinical appropriateness – with each denial generating appeals costs and payment delays that compound over time. For providers and patients, this increases billing uncertainty and may delay access to medically necessary diagnostics. Additionally, the TA process in particular requires significant documentation and staff time, while creating financial and administrative hurdles that are disproportionately challenging for small and mid-sized laboratories – especially those in rural or underserved areas.

More generally, we have concerns about any expansion of the MoDX Program, including nationwide, as we believe this would functionally create a de facto national coverage framework administered at the contractor level, instead of utilizing the formalized National Coverage Determination (NCD) process. The current NCD process utilizes a more robust transparency framework for developing national coverage policies using expertise that is available to CMS when making evidence-based policies (e.g. resources such as MEDCAC, USPSTF and CED). The NCD process also provides multiple formal opportunities for broad stakeholder participation and includes important procedural safeguards that are not present in contractor-based coverage frameworks.

We are also concerned about the structural/commitment conflicts inherent in maintaining a single MAC as the administrator of a proprietary program that is simultaneously utilized across Medicare and commercial markets. When one contractor – and a limited group of contractor personnel – administers a program that effectively influences coding identification, coverage determinations, and reimbursement decisions for both public and private payers, significant concentration of authority results. This concentration is further

amplified where program methodologies, review standards, and decision-making processes are not fully transparent to stakeholders.

Given these concerns regarding lack of transparency, the need for oversight guardrails, and the current absence of structural separation of functions in the integrity and impartiality of the MoIDX Program and the Z-code requirement, we urge the agency to evaluate its use of this program. Rather than expanding MoIDX at this time, we recommend CMS focus on targeted program integrity strategies and strengthening/reinforcing anti-fraud mechanisms already in place, including:

- Real-time data analytics to identify abnormal billing patterns or outlier tests without blocking routine, guideline-concordant care
- Targeted Probe and Educate (TPE) program, which MACs already use for provider-level review and education
- Claims edits and targeted medical review, including enhanced Medically Unlikely Edit (MUE) screens for high-volume molecular codes
- Automated prepayment review edits at the MAC level
- Clinical Laboratory Fee Schedule (CLFS) utilization data analysis to flag statistical outliers
- Evidence-based coverage linked to guidelines (CAP, NCCN, ASCO, ACMG, etc.) and collaboration with specialty societies to define appropriate use criteria
- Strengthened enforcement against kick-back arrangements and telemarketing-driven testing schemes

Finally, we note that clinical laboratories are already operating under significant reimbursement pressure as a result of PAMA-driven reductions to the Clinical Laboratory Fee Schedule, including approximately \$3.8 billion in cuts during the initial years of implementation. Although the statutory cap on annual reductions has been temporarily delayed through December 31, 2026, the underlying downward pressure on reimbursement remains substantial and ongoing. Layering additional administrative requirements associated with MoIDX, including TA processes and DEX Z-code compliance, onto already compressed payment rates further compounds this financial strain. These added costs and operational burdens are particularly acute for hospital outreach laboratories and independent laboratories serving rural and underserved communities, where margins are narrower and access to specialized reimbursement infrastructure is more limited. Absent careful consideration, such cumulative pressures risk undermining the financial sustainability of laboratories and, in turn, patient access to essential diagnostic services.

Summary

We appreciate the opportunity to provide these comments and welcome continued dialogue with the agency. Again, we share this Administration's commitment to program integrity and strongly support appropriate enforcement efforts. At the same time, we respectfully urge CMS to ensure any policy responses distinguish between documented fraud schemes and the broader field of molecular diagnostics. We also urge CMS to reevaluate its use of the MoIDX Program, as we have substantial concerns with the program today and we do not believe there is clear evidence it has materially reduced



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fraud, waste, or abuse. Instead, we recommend consideration of more targeted approaches and strengthening/reinforcing anti-fraud mechanisms already in place. Finally, we urge CMS to ensure that national Medicare coverage policies are developed through transparent, nationally accountable processes, not through expansion of contractor-administered frameworks that lack equivalent safeguards.

Please direct questions on these comments to Elizabeth Fassbender (202) 354-7125 / efassbe@cap.org.

Sincerely,

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