



March 30, 2026

Dr. Mehmet Oz  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Request for Information (RFI) Related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) - CMS-6098-NC**

Submitted electronically

Dear Administrator Oz:

On behalf of the Access to Comprehensive Genomic Profiling (ACGP) Coalition, thank you for the opportunity to comment on the Request for Information (RFI) related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH).

**About ACGP**

Access to Comprehensive Genomic Profiling (ACGP) is a collaborative coalition of leading molecular diagnostics companies and laboratories that aims to raise awareness about comprehensive genomic profiling (CGP) for advanced cancer patients. The coalition seeks to educate stakeholders about the value of CGP tests in all tumor types to facilitate appropriate use in the patient journey to inform medical management and improve clinical outcomes. Our membership is dedicated to sharing the clinical utility and economic value of CGP with healthcare stakeholders, thereby increasing access to this innovative technology in the United States.

ACGP supports CMS's efforts to address fraud, waste, and abuse in the healthcare system. In response to the RFI related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH), ACGP would like to raise a few key considerations for Section D: Reducing Medicare Fraud Related to Laboratory Tests Including Genetic Tests and Molecular Diagnostic Tests.

**I. Higher Utilization of Genomic Testing Reflects Scientific and Clinical Advancement, Not Overutilization**

ACGP recognizes that the January 2026 HHS Office of Inspector General (OIG) report highlighted that Medicare Part B spending on lab tests reached \$8.4 billion in 2024, with genetic tests accounting for 43 percent of that spending despite representing only 5 percent of test volume.[1] While these figures warrant further review, ACGP urges CMS to interpret this growth within the context of legitimate scientific advancement in precision oncology rather than as a proxy for fraud. The National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), and the European Society for Medical Oncology (ESMO) all recommend multigene panel-based genomic testing for patients with advanced cancers across an increasing number of tumor types.[2][3] The January 2025 NCCN guideline update for non-small cell lung cancer (NSCLC) alone added seven new recommended biomarkers.[4] Meanwhile, between August 2011 and September 2025, the FDA approved 35 premarket approvals and 403 supplements for oncology nucleic acid-based companion diagnostic test systems, each creating a clinical imperative for the

corresponding genomic test.[5] As the American Clinical Laboratory Association has noted, lab services remain less than 1 percent of total Medicare spending even as beneficiary access to genetic testing continues to grow.[6]

## II. Solutions for Distinguishing Legitimate Utilization from Fraud

ACGP urges CMS to adopt targeted oversight measures that distinguish between guideline-driven utilization and truly fraudulent activity, rather than implementing broad policies that could inadvertently reduce patient access to medically necessary testing. The recommendations below are focused specifically on CGP for advanced cancer patients; other clinically appropriate genetic and molecular diagnostic tests performed by legitimate laboratories are outside the scope of these recommendations. We recommend the following approaches:

### **Leveraging data analytics and coding transparency.**

Historically, CGP testing has not been highlighted as part of fraudulent activity. CMS's Fraud Defense Operations Center (FDOC) achieved \$1.8 billion in taxpayer savings in 2025, including over \$100 million related to suspect laboratories.[7] ACGP encourages CMS to continue expanding claims data analytics to identify suspicious ordering patterns, such as high test volumes lacking corresponding cancer diagnoses or ordering by providers who are not involved in the care management of patients being evaluated and treated for cancer. Critically, much of the fraudulent billing previously identified by CMS and the OIG has been associated with the misuse of non-specific Tier 2 molecular pathology CPT codes (81400–81408). In working with laboratories that provide the vast majority of CGP, we found that **these CPT codes are not utilized to bill for the CGP testing they are performing.**

**Strengthening safeguards while preserving access.** CMS should also consider requiring clinical laboratories performing high-complexity molecular diagnostic testing to maintain accreditation beyond baseline CLIA certification, such as accreditation by the College of American Pathologists (CAP), as a meaningful safeguard against low-quality or fraudulent testing operations. Past enforcement actions, including the 2019 DOJ case involving \$2.1 billion in fraudulent genetic testing and the 2024–2025 National Health Care Fraud Takedowns, involved clearly fraudulent schemes such as offering medically unnecessary cheek-swab tests at health fairs or nursing homes.[8][9] These patterns bear no resemblance to the ordering of guideline-concordant CGP by treating oncologists for patients with confirmed advanced cancer diagnoses. Broad policies such as shortened claims filing deadlines or burdensome prior authorization requirements could penalize legitimate laboratories and delay access to testing that directly informs treatment decisions for patients with life-threatening cancers.

## III. Considerations Regarding the MoIDX Program

CMS has indicated interest in exploring whether mandatory laboratory participation in the MoIDX program could serve as a mechanism to mitigate fraud, waste, and abuse. While MoIDX is primarily designed to establish coverage, coding, and reimbursement standards for molecular diagnostic testing, laboratories may enroll their tests in the DEX™ Diagnostics Exchange Registry without formal review by MoIDX. This public-facing registry includes basic laboratory identifiers and, at the laboratory's discretion, information about specific tests. Inclusion in the registry, however, does not imply that a test is covered under a MoIDX Local Coverage Determination (LCD), nor does it imply that a full Technology Assessment has been completed.



While the DEX registry may offer some value to payers assessing coverage or payment decisions, it is not well suited as a primary means to identify or prevent fraud, waste, and abuse. Much of the laboratory-level data mirrors information already available through the CLIA database. The registry does not provide visibility into claim validity, test performance, clinical justification for ordering, or whether test results lead to clinically actionable outcomes. ACGP is also concerned about expanding MolDX's scope nationwide given existing capacity limitations. Palmetto GBA currently lacks sufficient resources to support MolDX's foundational responsibilities, resulting in substantial delays in coverage determinations and LCD development, with some submissions remaining unresolved for over two years.

Notwithstanding these operational challenges, when available, MolDX LCDs typically include detailed medical necessity criteria that help guide appropriate utilization and reimbursement. By contrast, LCDs issued in non-MolDX jurisdictions, such as those administered by First Coast and Novitas, often lack comparable specificity, which may create opportunities for inappropriate or fraudulent billing. Implementing uniform, clearly defined coverage policies across all Medicare Administrative Contractor jurisdictions could strengthen program integrity and reduce the risk of improper payment of not medically necessary and/or fraudulent claims.

## **Conclusion**

For millions of Americans living with advanced cancer, access to comprehensive genomic profiling is not an abstract policy question. It is the critical first step toward identifying whether a targeted therapy may extend or save their life. ACGP shares CMS's commitment to eliminating fraud, waste, and abuse, and we firmly believe this goal can be achieved without undermining the remarkable progress that precision oncology has made possible. The fraudulent actors who have exploited Medicare through medically unnecessary testing schemes should be held accountable through targeted enforcement, enhanced coding transparency, and stronger laboratory quality standards. But the solution must not inadvertently sweep in the legitimate, guideline-driven testing that patients and their oncologists depend on every day. We respectfully urge CMS to ensure that the CRUSH rulemaking protects both the integrity of the Medicare program and the ability of advanced cancer patients to access the diagnostic tools that modern medicine demands.

We appreciate your consideration of our comments. Should you have any questions or require our expertise, please direct your correspondence to [esmith@conafaygroup.com](mailto:esmith@conafaygroup.com).

Respectfully submitted,

**Access to Comprehensive Genomic Profiling (ACGP) Coalition**

## References

1. HHS Office of Inspector General, "Total Medicare Part B Spending on Lab Tests Rose in 2024, Driven by Increased Spending on Genetic Tests," Report No. OEI-09-25-00330, January 23, 2026.
2. Ali SM, et al., "Comprehensive Genomic Profiling Facilitates Implementation of the NCCN Guidelines for Lung Cancer Biomarker Testing," *The Oncologist*, 2016;21(11):1374-1380.
3. Remon J, et al., "Next-Generation Sequencing in Oncology: A Guiding Compass for Targeted Therapy and Emerging Applications," *Cancers*, 2025;17(7):1225.
4. Kris A, et al., "Do Targeted NGS Panels Include NSCLC Guideline-Recommended Biomarkers?" *American Journal of Managed Care*, February 2026.
5. FDA, "Immunology and Microbiology Devices; Reclassification of Nucleic Acid-Based Test Systems for Use With a Corresponding Approved Oncology Therapeutic Product," 90 Fed. Reg. 94160, November 25, 2025.
6. Healthcare Dive, "Genetic Tests Come Under Scrutiny in Trump Administration's Fraud Crackdown," March 2026.
7. CMS, "Request for Information Related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH)," 91 Fed. Reg. 9803, February 27, 2026.
8. HHS Office of Inspector General, "CMS's Oversight of Medicare Payments for the Highest Paid Molecular Pathology Genetic Test Was Not Adequate To Reduce the Risk of up to \$888 Million in Improper Payments," Report No. A-09-21-02007, June 2023.
9. U.S. Department of Justice, "Federal Indictments and Law Enforcement Actions in One of the Largest Health Care Fraud Schemes Involving Genetic Testing," 2019.