ASSOCIATION FOR MOLECULAR PATHOLOGY
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March 30th, 2026

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

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

Submitted electronically via regulations.gov

Dear Administrator Oz:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments in response to the Request for Information (RFI) Related to Comprehensive Regulations To Uncover Suspicious Healthcare (CRUSH) - CMS-6098-NC. AMP is an international medical and professional association representing approximately 3,100 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry. AMP members are highly involved in the development, validation, and interpretation of molecular diagnostic tests, including biomarker tests for the diagnosis and management of inherited disorders, cancers, rare and infectious diseases.

Efforts to Address Fraud Must Preserve Patient Access to Laboratory Tests

AMP believes that preventing and reducing fraud in Medicare is a high priority and stands ready to leverage the expertise of its membership to assist the Centers for Medicare and Medicaid Services (CMS) in strengthening program integrity to ensure the appropriate billing for laboratory tests while preserving patient access to legitimate genetic testing. The laboratory services provided by our members have been instrumental in improving patient outcomes and saving healthcare costs. For example, in February, the Food and Drug Administration updated the label for the cancer chemotherapy, capecitabine and fluorouracil (5-FU), to include risks associated with dihydropyrimidine dehydrogenase (DPD) deficiency.[1] The *DPYD* gene encodes an enzyme that breaks down this drug, and patients with certain variants in the *DPYD* gene lack this enzyme, making exposure to this medication toxic and at risk for adverse events, including death. The Boxed Warning now recommends molecular genetic testing prior to initiating this treatment to protect patients from these dangerous and costly

[1] https://www.fda.gov/drugs/resources-information-approved-drugs/safety-labeling-update-capecitabine-and-fluorouracil-5-fu-risks-associated-dihydropyrimidine

adverse events. Toxicity from 5-FU is estimated to be responsible for more than 1,300 deaths per year,[2] and studies also show that pre-treatment *DPYD* genotyping is cost-effective[3] by reducing adverse event-related hospitalizations among variant carriers.[4]

To further illustrate the value and importance of molecular laboratory testing, technological advancements in genetic sequencing have enabled the development of extensive mutational and molecular biomarker profiling of patients' tumor samples. This has been parallel with the explosive development of molecular targeted pharmaceuticals. In oncology, the percentage of clinical trials incorporating mutation and molecular biomarkers has risen from 18 percent in 2000 to 61 percent in 2019.[5] This important work has led to the availability of 286 molecular targeted therapies for patients in 2020, a greater than 350% increase from the 81 therapies available in 2012. The National Cancer Institute lists on its website that there are now dozens of FDA-approved targeted therapies available for more than 30 different types of cancer.[6]

Molecular genetic testing helps to precisely define the appropriate use of molecular targeted therapies and has been shown to improve patient outcomes and survival, and lead to cost savings because of the more effective and efficient implementation of these therapies. In a cost/value analysis study by AMP members, increasing the use of genetic testing in patients with advanced non-small-cell lung cancer led to a theoretical increase in the use of targeted therapy (6% to 13%), accompanied by a dramatic decrease in the use of nontargeted therapy (83% to 20%).[7] In other words, care would de expected to be better optimized, and in patients with non-small cell lung cancer (NSCLC), a greater number of patients would expect to be treated with precision medicines that were more likely to improve their outcomes (e.g., longer progression-free survival and fewer adverse events). In addition, the use of genetic testing results would be expected to greatly increase the percentage of patients eligible for enrollment in clinical trials. Importantly, the study showed that the total cost of treatment would decrease by $2.7 million (from $10.2 million to $7.5 million) when a patient with NSCLC undergoes genetic testing. These examples highlight why efforts to address fraud in laboratory test payment need to protect beneficial medical practice and patient access.

Current Coding Manuals and Systems Foster Program Integrity

The vast majority of clinical laboratories in the United States are working to serve their patients and physician clients. They do not engage in billing fraud by adhering to the coding and billing practices dictated in the Medicare National Correct Coding Initiative (NCCI) Manual for laboratory services, which

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[2] National Institutes of Health, Public Health Service, HHS. Public teleconference regarding licensing and collaborative research opportunities for: methods and compositions relating to detecting dihydropyrimidine dehydrogenase (DPD). Fed Regist. 2008;73:38233.

[3] Brooks GA, Tapp S, Daly AT, Busam JA, Tosteson ANA. Cost-effectiveness of DPYD Genotyping Prior to Fluoropyrimidine-based Adjuvant Chemotherapy for Colon Cancer. Clin Colorectal Cancer. 2022;21(3):e189-e195. doi:10.1016/j.clcc.2022.05.001

[4] Sarah Morris et al. Cost analysis of pre-treatment dihydropyrimidine dehydrogenase (DPYD) genotyping to reduce hospitalizations at a cancer center in the United States (U.S.).. J Clin Oncol 43, 3097-3097(2025). DOI:10.1200/JCO.2025.43.16_suppl.3097

[5] Personalized Medicine Coalition, "The Personalized Medicine Report: 2020, Opportunity, Challenges, and the Future." 2020. http://www.personalizedmedicinecoalition.org/Userfiles/PMCCorporate/file/PM_at_FDA_The_Scope_and_Significance_of_Progress_in_2019.pdf Accessed August 19, 2021.

[6] https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/approved-drug-list

[7] Sabatini LM, Mathews C, Ptak D, et al. Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology. J Mol Diagn. 2016;18(3):319-328. doi:10.1016/j.jmoldx.2015.11.010

is intended to promote national, consistent coding methodologies and control improper, inappropriate payments for Medicare Part B claims. AMP participates in the comment process to update the Manual to support CMS's efforts to ensure that coding instructions reflect the appropriate care provided to patients.

AMP has always advocated directly with private and public payors in support of requiring that the most descriptive and applicable codes be used on claims, which provides needed transparency into procedures performed. Specifically, the codes listed on a claim may be an early indicator of its legitimacy. AMP was instrumental in the development of the Tier 1 and Tier 2 molecular pathology codes, which established gene-specific codes to help payors understand the purpose of the billed test. Since then, as innovation in testing has evolved from targeted testing to whole genome analysis, new codes for genomic sequencing procedures have been established to ensure that payors, including Medicare, continue to have full transparency into the tests for which claims are submitted. AMP actively engages in the code development process, the annual Clinical Laboratory Fee Schedule process, and more, all to foster transparency in coding and payment for the genetic and genomic testing its members provide.

Recommendation #1: AMP encourages CMS to reinforce NCCI Manual requirements for coding requirements for molecular pathology codes.

Recent Patterns of Fraud Reveal Opportunities to Prevent Future Cases

Recent investigations and prosecutions of fraud in genetic testing provide lessons on how to detect fraud early to intervene and prevent wasted funds. For example, in 2022, one industry analyst cross-referenced case information from defendants recently charged by the Department of Justice[8],[9] with data from CMS[10] on all payments made to providers and laboratories in 2020 and found:[11]

- One of the laboratories indicted received over 95% of their reimbursement using Tier 2 codes, 50% of which were the same code, 81408. This CPT code is used for the full sequencing of genes implicated in rare diseases, typically diagnosed in childhood, and thus, is not typically used in the Medicare population. In 2018, the code was priced at $2000 as a result of the implementation of Section 216 of the Protecting Access to Medicare Act (Public Law No: 113-93). Subsequently, use of the code in Medicare claims grew substantially and that same laboratory involved in the fraud case was billing Medicare for this code up to four or five times for each patient (claims of up to $10,000 per test). The increased utilization of codes such as 81408 occurred in 2019 before the COVID-19 pandemic and prior to the telehealth flexibilities, indicating that telehealth did not play a role in instances of fraudulent billing for these laboratory tests.
- Further, when analyzing claims by state for these codes rarely used in the Medicare population, 85% of the payments were made to laboratories in Texas (56%), Florida (18%),

[8] https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud

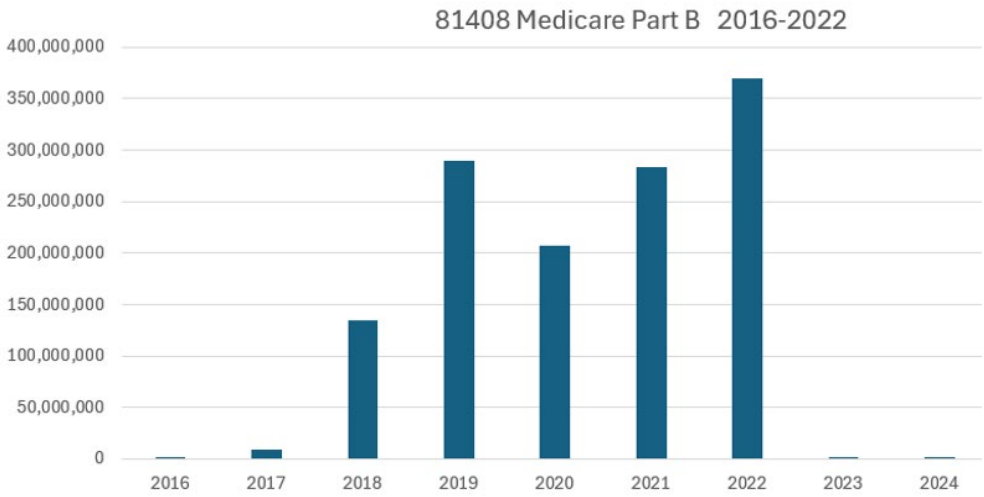
[9] https://www.justice.gov/criminal-fraud/telemedicine-court-documents

[10] https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-provider-and-service

[11] https://www.youtube.com/watch?v=LQ4URECsQ9s

and Louisiana (11%). These three states are within two specific Medicare Administrator Contractor (MAC) jurisdictions, suggesting that certain MAC practices may be more vulnerable to fraud than others.

After the prosecution of this case in 2022 revealed the fraud, including the failure of two MACs to recognize the misuse of this code, Part B claims for 81408 nearly ceased:



Source: https://www.discoveriesinhealthpolicy.com/2026/03/the-crush-initiative-and-medicares-bone.html

However, 2024 claims data showed an uptick in claims from laboratories in Florida and Texas for the code 81419, a panel for epilepsy priced at $2449.[12] In alignment with this finding, the 2024 HHS Office of Inspector General report, "Total Medicare Part B Spending on Lab Tests Rose," indicates that spending for 81419 increased by 392% from 2023 to 2024.[13] Again, epilepsy is most commonly diagnosed in childhood and a significant increase in the use of this test in the Medicare population warrants immediate investigation.

In addition, despite these obvious patterns and red flags indicative of fraud, MACs continued to process suspect claims. These patterns are easily revealed by simply examining claims data without complex algorithms, methodology, etc. Flagging a claim that includes multiplies of a code for testing associated with a pediatric indication should have been sufficient information for a MAC to have denied the claim, or at the very least, investigated it prior to issuing payment. To assist MACs with improving their abilities to identify claims suspicious of fraud, CMS could implement a pilot program that uses software, i.e., predictive algorithms, to identify these patterns. Further, the agency should assess its regulatory authority to audit MACs' ability to recognize patterns of fraud and consider the feasibility of monetary penalties for those who repeatedly fail to act in light of these red flags.

Recommendation #2: Monitor changes in code utilization in claims data across MAC jurisdictions and require that MACs investigate unexpected or unexplained increases for inappropriate utilization.

[12] https://www.discoveriesinhealthpolicy.com/2026/03/the-crush-initiative-and-medicares-bone.html
[13] https://oig.hhs.gov/documents/evaluation/11453/OEI-09-25-00330.pdf

Recommendation #3: Implement a pilot program to test the use of predictive algorithms to detect fraud in claims and alert MACs to possible fraudulent activity.

Recommendation #4: Routinely audit MACs and consider penalties for MACs who repeatedly fail to take action to prevent fraud in their jurisdictions.

Recommendation #5: Conduct a comprehensive evaluation to understand why some MAC jurisdictions are better equipped to prevent fraud than others.

Leverage CLIA Program to Assist with Fraud Prevention Efforts

Further, many of the laboratories involved in these cases are new and lack established histories of providing clinical care. In fact, the Healthcare Fraud Prevention Partnership 2020 white paper found red flags indicating fraud, such as the laboratory was not equipped to perform genetic testing and the laboratory's location was a UPS store, retail business, or a home business.[14] In 2020, when the country faced challenges in meeting testing capacity for the SARS-CoV2 pandemic response, hundreds of new laboratories without proper credentials began offering COVID-19 testing. CMS administers the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program which sets federal standards for all laboratories that test human specimens for health assessment or to diagnose, prevent, or treat disease. In October 2020, CMS issued 171 cease and desist letters to laboratories operating in violation of CLIA, with 34% of them sent to laboratories lacking a CLIA certificate, meaning it was illegal for them to test human samples.[15] MACs taking steps to assure that a clinical laboratory is appropriately accredited and credentialed to provide patient care prior to processing a claim is not only an easy tactic to minimize fraud, but one that should routinely happen to assure patient safety.

Recommendation #6: Direct MACs to screen laboratories to assure their legitimacy and credibility, i.e., confirm CLIA certificate, physical place of business, licensure of medical professionals employed, etc.

Recommendation #7: Increase funding for CLIA to fulfill program requirements, to provide regular inspections of clinical laboratories in the United States and improve the database of CLIA certified laboratories so that it is up to date, easily searchable, and readily available to the public.

OIG Report Expected by 2028 will Provide Additional Actions to Prevent Fraud in Laboratory Testing

The FY2026 Consolidated Appropriations Act (Public Law No: 119-75), recently signed into law by the President, included Section 6212, Enhancing Certain Program Integrity Requirements for DME Under Medicare, which directs the HHS Office of the Inspector General by January 1, 2028 to submit to Congress a report assessing fraud risks related to clinical laboratory tests and effective tools for reducing such fraudulent claims. The report will provide information on which, if any, tests are at high risk, an analysis of whether CMS can detect aberrant billing patterns in a timely manner, strategies for

[14] https://www.cms.gov/files/document/hfpp-genetic-testing-fwa-white-paper.pdf

[15] https://www.cms.gov/newsroom/press-releases/cms-takes-action-protect-integrity-covid-19-testing

identifying and monitoring providers who are outliers, etc. This information will be incredibly informative to policymakers, including the CRUSH initiative, by providing insights into how to best identify and prevent fraud in genetic testing without needlessly restricting patient access. AMP is hopeful this report will reveal much of the information discussed above in our comments to the RFI and affirm our belief that fraud in genetic testing is easily preventable by assuring the credibility of providers and monitoring for unusual coding strategies and patterns in claims. This will enable the agency to focus its resources and efforts on the most effective approaches rather than taking unnecessarily aggressive steps that will restrict legitimate patient care.

As CMS continues its efforts to address the risk of fraud in laboratory testing, AMP cautions against tactics that limit access to genetic testing via telehealth. Typically, ordering a genetic test does not require a physical examination, but rather is often ordered based on an individual's personal and family history, which can easily be obtained via telehealth. It has been a valuable tool that improves access to genetic counseling that informs the use of cancer genetic testing as shown in the ENGAGE Study.[16] Researchers found that remote access to these professionals improves the use of clinically recommended genetic testing, and this has a direct impact on patient care – notably, 10 percent of patients who completed testing after receiving telehealth care had clinically actionable results. These results could, for example, help to ensure that a patient with an inherited mutation in *TP53*, who would face a very high risk of developing cancers, is provided with additional cancer screening services.

Leveraging telehealth to expand patient access to care is critical as the United States faces an ongoing shortage of genomics health professionals. In 2020, the U.S. Government Accountability Office found the number of medical geneticists and genetic counselors varies significantly by geographic region and state, with only 4,700 genetic counselors and 1,240 medical geneticists serving the entire country.[17] Southern states in addition to certain midwestern and western states, tended to have a lower number of medical geneticists and genetic counselors per 500,000 people. At that time, three states, West Virginia, Mississippi, and Wyoming, had fewer than one genetic counselor per 500,000 people. As genetic testing is increasingly incorporated into medical practice, patients will need access to genomics professionals because they are important for optimizing care and ensuring that clinically appropriate tests are being ordered.[18] Given the state of the workforce, telehealth will be a critical tool to ensure access in rural and other communities lacking these professionals.

As discussed earlier in our comments, given that fraudulent ordering of laboratory testing may be easily identified through extra scrutiny on the use of specific codes in certain MAC jurisdictions, rather than adding additional barriers that restrict patients from accessing laboratory testing services through telehealth, CMS should explore the adoption of tools and processes, possibly including artificial intelligence, that can detect patterns of fraud enabling MACs the opportunity to intervene and prevent waste.

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[16] Henderson TO, Egleston B, Howe S, et al. The ENGAGE Study: A Randomized Trial Optimizing Uptake of Germline Cancer Genetic Services in Childhood Cancer Survivors. Preprint. medRxiv. 2025;2025.10.20.25338173. Published 2025 Oct 22. doi:10.1101/2025.10.20.25338173

[17] https://www.gao.gov/products/gao-20-593#summary

18 Conway ME, Kalejta CD, Sternen DL, Singh IR. The Importance of Genetics Experts in Optimizing Genetic Test Orders Through Prospective and Retrospective Reviews. Am J Clin Pathol. 2020;153(4):537-547. doi:10.1093/ajcp/aqz188

Recommendation #8: Before implementing any policy changes that will restrict legitimate patient access to lifesaving tests, wait for recommendations from the anticipated OIG report.

Recommendation #9: Support efforts to expand the number of genomics professionals including funding training programs and advocating for doctoral scientists to be qualified healthcare providers under Medicare.

Prevent MAC Consolidation

The RFI also requests information on the Molecular Diagnostic Services Program (MolDX) administered by Palmetto GBA on behalf of CMS, including whether requirements to register tests in the MolDX program meaningfully address fraud, waste, and abuse. MolDX was neither created nor designed to detect and prevent fraud. While compliance with the program's additional requirements to obtain coverage, such as securing a Z-code, completing a technical assessment and satisfying other administrative steps adds procedural hurdles to obtain reimbursement, it is a significant assumption to believe that this will deter determined actors engaged in fraudulent activity. Moreover, although AMP and its members have generally had positive experiences working with MolDX's current leadership, this has not been uniformly true over time. In our and our members' experience some MACs have been less effective in serving as operational contacts and in bridging the gap between payer and provider communities. Consolidating coverage decisions for all molecular pathology procedures under a single MAC places substantial reliance on consistent, effective engagement with medical directors and other key decision makers—an experience that is often variable and subjective.

We are concerned that consolidating all states under MolDX would erode the utility of local coverage determinations (LCDs) and result in an LCD having the breadth of a de facto national coverage determination (NCD) for molecular pathology codes. A multiple-MAC system allows patients and providers to advocate directly with their respective MACs and fosters meaningful scientific discourse tailored to regional practice patterns and patient populations. For instance, the importance of a multiple-MAC system has been made abundantly clear to AMP during our work responding to draft local coverage determinations. Though some MACs release similar draft LCDs for an assay, they often respond differently to AMP's presentation of scientific evidence in a manner that reflects their local constituencies' needs.

Further consolidation of MAC authority would limit opportunities for patient and provider engagement, reduce competition, and diminish varied input brought to coverage decisions, each of which is essential to ensure that the full scope of evidence and real-world experience is considered. AMP supports expanded opportunities for stakeholders to weigh in before MACs implement changes. Losing this diversification would be particularly detrimental in molecular diagnostics, a field characterized by rapid scientific advancements and technological innovation. Practitioners and stakeholders at AMP and other specialty groups actively monitor developments in the field as they occur. It is necessary for MACs to incorporate the expertise of stakeholders such as AMP and other authoritative resources to ensure that coverage determinations are made using the most current and robust scientific evidence. For these reasons, we strongly caution against CMS giving such broad authority to a single MAC and weakening the benefits inherent in the LCD process.

As referenced above, MolDX requires laboratories to participate in its proprietary Z-code program, obtain a unique Z-code for each of their tests, and reference this code when filing claims. Private payors, including United Healthcare, have adopted components of the MolDX program including obtaining and filing claims with Z-codes. While the Z code program may have been initially intended to enhance transparency regarding a test's intended use, the cost, time, and resource burden associated with securing Z-codes and completing associated technical assessments has been significant for AMP members. It is also important to highlight that the program has not improved transparency for the public, which is another CMS priority. In practice, MolDX has increasingly directed laboratories to use CPT code 81479, which is intended for unlisted molecular pathology procedures and lacks a publicly established Medicare payment rate. Procedures billed under 81479 are not set through the public CMS CLFS payment rate setting process, and are not subject to the reporting requirements in Section 216 of the Protecting Access to Medicare Act of 2014 (Public Law No: 113-93). Instead, payment rates are set by Palmetto and the MolDX program and vary considerably. As a result, it is unclear to the public when 81479 is billed what services are being provided and what Medicare is paying for those services. The combined use of Z-codes and unlisted CPT codes also discourages the development of new CPT codes, which, historically supported transparency and coding specificity. AMP believes that the current CPT code set, which is also the only HIPAA-compliant code set available, along with ongoing efforts to expand it to capture new intended uses and emerging technologies provides sufficient granularity for payors to assess the clinical intent and appropriateness of the molecular pathology procedures submitted in the claim.

Further, Palmetto GBA monetizes the data derived from the Z-code program by selling the data for market analysis and other commercial purposes. While such practices may be acceptable in a voluntary program and in the private sector, it raises concerns if CMS were to mandate nationwide participation in MolDX. Under such circumstances, it is questionable whether a CMS contractor should financially benefit from data generated through a taxpayer funded program.

If there are successful practices that MolDX has adopted that, for example, ensure legitimate patient-provider relationships or prevent certain tests from being inappropriately ordered too frequently in a patient encounter or over another period of time, then those tactics should be reviewed, and CMS should develop MAC best practices. Adoption of those best practices would promote quality across all MACs and should be pursued in lieu of consolidation under a single MAC program, especially given concerns about de facto national coverage policies being written by a MAC and the proliferation of entities using non-HIPAA-compliant code sets.

Recommendation #10: Continue to support a robust multiple-MAC system.

Recommendation #11: Evaluate MAC strategies that promote appropriate billing and reimbursement and develop best practices for adoption across all MACs.

In summary, AMP believes there are immediate actions CMS and MACs can take to prevent future instances of fraud, and that perhaps, would have even prevented recent cases from happening in the first place. We encourage the agency to leverage existing programs to prevent fraud, e.g. NCCI Manual, CPT coding system, CLIA program, etc., and direct MACs to take proactive actions to identify suspicious claims, laboratories without appropriate accreditation, and other indicators of potential fraud. The

anticipated OIG report will hopefully provide additional recommendations that reflect the importance of balancing these measures with patient access to genetic testing.

Thank you very much for your consideration of our response to the CRUSH RFI. AMP hopes to be a resource and partner in your efforts to reduce and prevent fraud in genetic testing while maintaining patients' appropriate access to testing. Please contact Samantha Pettersen, Public Policy Manager at Spettersen@amp.org if we can be of further assistance.

Sincerely,

Aaron Bossler, MD PhD
President, Association for Molecular Pathology