CAPITOL STREET

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OIG Study Examining Genetic Test Fraud Due 2028

Targeted Program Integrity Effort Aligns With CRUSH RFI

Relevant Companies

Our Take & Next Up

A government study announced June 15 will look into genetic test fraud, in line with our thesis on Medicare's CRUSH RFI as leading to more regional oversight. The study was mandated by the FY 2026 Consolidated Appropriations Act (here) and not brand new. The CMS Office of the Inspector General (OIG) study, targeted for completion by Jan 1, 2028, will evaluate ways to strengthen oversight of Medicare Part B genetic testing, including identifying fraud risks, analyzing provider trends, and assessing geographic differences, particularly between MolDX and non-MolDX jurisdictions.

Key Points

We have said that Medicare's CRUSH RFI will likely lead to targeted fraud enforcement (like this study) over a nationalized MolDX or blunt policies that restrict legitimate diagnostics and precision medicine innovation (our take here).

In the meantime, PAMA data reporting is ongoing.

- **CMS is collecting data under the PAMA data reporting requirement.** We understand that CMS looks to address outlier data as it comes in.
- **We see no major ADLT structure changes near-term**, as there is no current legislation or CMS push for reform. Stakeholders generally view Advanced Diagnostic Laboratory Test (ADLT) and Proprietary Laboratory Analyses (PLA) pathways as functioning well for innovative diagnostics and supporting faster reimbursement.

In 2026-27, OIG will examine avenues for strengthening oversight of genetic tests covered under Medicare Part B. OIG notes that the rapid emergence of new genetic tests and their higher average per-test payment amount can make them vulnerable to fraud, waste, and abuse. The agency notes that Medicare Part B spending on genetic tests has been climbing steadily, with 2024 expenditures topping $3.6 B – a half-billion-dollar increase over the prior year. We note that this is a relatively small percentage of overall Part B spending, estimated to be around $633 B in 2026 (here).

Overall, our take. Capitol Street hosted a webinar on the CRUSH RFI, coverage and payment for genetic tests and other molecular diagnostics topics on May 22 (link here). Major takeaways are below.

CRUSH RFI & MEDICARE FRAUD IN DIAGNOSTICS

While fraud exists in Medicare, it's not widespread – concentrated in two states (Florida and Texas) and two Medicare Administrative Contractors (First Coast and Novitas). The CRUSH RFI highlights concerns over lab testing's share of Medicare fee-for-service spending and potential fraud. By and large, stakeholders believe that the best approach is to use claims data analytics to flag outliers in molecular diagnostics claims (strip-mall/UPS-store labs, inappropriate code usage).

The CRUSH RFI will likely result in targeted fraud enforcement by CMS and OIG, rather than broad diagnostic access restrictions. We hosted a webinar with a genetic counselor and policy expert in DC last month. She concurred that there will likely be more surgical strikes from Medicare to root out fraud, waste, and abuse in molecular diagnostics.

- For example, Operation Double Helix ($10 B scandal) involved improper telehealth-style health fairs at senior centers with inadequate patient consent (here).
- Post-prosecution, some labs shifted to billing inappropriate pediatric codes (e.g., epilepsy) for Medicare-aged beneficiaries.

We could see stronger accountability requirements for MAC contractors to identify outlier billing patterns and suspend questionable claims. Our speaker specifically called out First Coast and Novitas as contractors that need guidelines to ensure program integrity. MACs already use tools like prior authorization, payment review and claims monitoring across Medicare and should be expected to identify these billing patterns in lab settings to help decrease fraud.

MOLDX

We don't anticipate a nationalized MolDX as contemplated in Medicare's CRUSH RFI. A consolidated MolDX would likely reduce transparency and regional flexibility. The recent departure of MolDX Medical Director, Gabriel Bien-Willner, MD, PhD (here), also signals a potential shift in policy direction. The molecular diagnostics industry (ABT, CAI, DGX, GH, LH, MYGN, NTRA, TEM) opposes nationalizing MolDX as a national program would do little to prevent fraud in genetic testing and would create a de facto national coverage system.

Stakeholders have argued that MolDX was not designed as an anti-fraud program, and expanding it nationally would not necessarily help fraud prevention. MolDX's success has historically been tied to its leadership and technical assessment processes. LCDs (local coverage determinations) are different from CMS's NCD (national coverage determination) process and as regional needs vary, LCDs generally involve less formalized transparency.

ADLT PRICING & PATHWAYS

We don't foresee administrative or legislative risk to ADLTs any time soon. ADLTs are not addressed in the CRUSH RFI and meaningful changes would likely require legislation that has not been proposed. Any reform is more likely to emerge in a future legislative cycle, such as the 2027 MDUFA reauthorization or later health policy packages.

Will CMS flex its regulatory muscle? The ADLT pathway and PLA codes are working well for innovative tests.

- According to our expert, there has been a sharp increase in PLA codes submitted for Medicare Clinical Lab Fee Schedule (CLFS) pricing (here). However, stakeholders are pleased with the ADLT program and there is no signal that CMS is looking to implement changes, despite high margins.
- ADLTs allow faster reimbursement and premium pricing (initial 3 quarters) compared to traditional CPT processes, allowing reimbursement to keep pace with innovation. Academic societies often do not support proprietary PLA tests, signaling they primarily benefit single labs.

Pending CMS meetings this summer (July 14-15) and fall (Sept. 15-16) are unlikely to address ADLTs overall. CMS will host two Medicare Advisory Panel Meetings on Clinical Diagnostic Laboratory Tests (CDLTs) on July 14-15 and Sept. 15-16 (here). The PAMA data reporting period for CDLTs goes from May 1 to July 31, followed by data analysis and proposed & finalized pay determinations in the fall and new rates effective Jan. 1, 2027 (timeline here).

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