CAPITOL STREET

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CRUSH: National MolDX Program Unlikely Near-Term

Targeted Fraud Enforcement (Non-MolDX) Areas Likely

ADLTs May Be Safe for Now As PAMA Data Become Available

Relevant Companies

Our Take & Next Up

We don't anticipate a nationalized MolDX as contemplated in Medicare's CRUSH RFI. The molecular diagnostics industry (CAI, DGX, EXAS/ABT, GH, LH, MYGN, NTRA, TEM) argues that a national MolDX would do little to prevent fraud in genetic testing and would create a de facto national coverage system by consolidating oversight under a single Medicare Administrative Contractor (MAC).

While the RFI could eventually lead to rulemaking or sub-regulatory guidance, we believe targeted fraud enforcement by CMS and OIG is likely the first near-term outcome. We don't see administrative or congressional risk to ADLTs any time soon, either, despite genetic testing called out as 43% of FFS lab spend (OIG, 2024). Some have questioned whether premium Medicare reimbursement for Advanced Diagnostic Lab Tests (ADLTs) could get swept up with new efforts to fight fraud, waste, and abuse. However, changing the ADLT structure would likely require legislation (no such legislation has been proposed).

Still, CMS could adjust ADLT pricing downward. Recall, PAMA data collection of lab-reported pricing for Clinical Diagnostic Laboratory Tests (CDLTs) is ongoing (5/1-7/31 reporting period), with data analysis and public meetings in the summer, proposed & finalized pay determinations in the Fall, and new rates effective Jan. 1, 2027 (timeline here). Data on ADLTs are delivered to CMS annually, with new ADLTs required to submit data during the sixth month of their ADLT initial period (ADLT guidance here). By statute (here), ADLT manufacturers enjoy pricing for three calendar quarters (initial period); then, CMS may adjust prices based on the weighted median of private payor rates.

Key Points

CRUSH RFI

A nationalized MolDx is unlikely. The lab industry opposes a nationalized MolDX program. Molecular diagnostics companies have had challenges navigating the MolDX program with varying success in gaining Medicare coverage and payment for their tests.

What is MolDx? MolDX, run by Medicare contractor Palmetto GBA (here), provides a process for obtaining coverage based on evidence of clinical utility (does the test provide actionable data that improves net health outcomes). However, the bar for clinical utility is often subjective, based on who is serving as the medical director for MolDX at the time.

MolDX requirements are often burdensome for lab companies.

- Under the MolDX program, most lab companies are required to attain a proprietary Diagnostics Exchange (DEX) "Z-code" for tracking tests (here) and must also undergo a Technology Assessment (TAs) to demonstrate clinical utility (here).
- This process is *not* always straightforward and can be costly and time consuming.
- The MolDX program works well for well-established labs with one or two Advanced Diagnostic Laboratory Tests (see below), but that is *not* the case for all labs.

Extending the reach of MolDX to the remaining jurisdictions would give Palmetto GBA a monopoly over all molecular diagnostics policy decisions within Medicare. MolDX already has jurisdiction over the majority of coverage and payment for molecular diagnostics in Medicare. MolDX has seven jurisdictions (JM A/B, JJ A/B, JE A/B, JF A/B, J5 A/B, J8 A/B, and J15 A/B) for payers in 30 U.S. states and territories (here).

There are stakeholder concerns that MolDX monetizes their DEX registry with potential conflicts of interest. The DEX Diagnostics Exchange (here) is a platform that Palmetto uses for molecular diagnostic test identification and policy management. Stakeholders have questioned whether there is a conflict of interest for CMS to mandate everyone pay to obtain a DEX "Z code" when Palmetto then profits. There have also been concerns that the MolDX Medical Director, Gabriel Alejandro Bien-Willner, MD, PhD, may personally benefit from MolDX with the ties to his molecular diagnostics consulting business (here).

MolDx Fraud Cases Are Largely Regional (FL/TX)

Lab companies call for more targeted enforcement rather than a nationalized MolDX program. Comments on the Feb. 27 CRUSH RFI were due March 30 (comments here). Stakeholders pointed out that most cases of fraud in the molecular diagnostics space (inappropriate codes, billing outliers, etc.) are centered in a few non-MolDX states, such as **Florida** (managed by First Coast MAC) and **Texas** (managed by Novitas MAC). Additionally, MACs in these states have since worked to address issues identified by OIG, including the practice of "code-stacking," or billing multiple CPT codes for a single molecular diagnostic test, particularly in Tier 2 (81403–81408) and unlisted code 81479 (FCSO coverage article here).

The Office of Inspector General (OIG) identified up to $888.2 M in improper payments for 450,000+ tests using CPT code 81408 from 2018 to 2021.OIG noted that this code is tied to rare childhood diseases, which is uncommon in Medicare's older population. According to OIG, this specific problem has since been corrected (no payments for this code by the end of 2021); however, we expect CMS and OIG will keep a close eye on genetic testing claims going forward, particularly in non-MolDX areas.

We don't see administrative or congressional risk to ADLTs any time soon. There has been some concern over whether CMS will look to rein in the ADLT structure; however, we don't see that happening any time soon as there is no mention of ADLTs in the CRUSH RFI and changing the ADLT structure would likely require legislation (no such legislation has been proposed). We don't think there's an appetite or vehicle for Congress to

take on ADLT reform this year, but it could crop up in the next MDUFA reauthorization in 1H 2027 (Oct. 1, 2027 deadline) or other pending legislation 2027+.

What are ADLTs? Since the enactment of PAMA, 18 lab tests (includes tests made by BDSX, CSTL, FMI/RHHBY, GH, MYGN, NTRA, TEM, VCYT) have been afforded premium Medicare reimbursement after being granted an ADLT designation (full list here). Recall, ADLT status allows a test to be paid at the actual list charge for the first three calendar quarters (initial period), and then at the weighted median of private payor rates (ADLT Guidance here). Despite an annual reporting requirement, the vast majority of ADLTs have been able to *maintain* higher reimbursement after the initial period.

Clinical Labs Push for PAMA Reform

Coming soon: More recent lab pricing data as required under PAMA will be delivered to CMS. PAMA cuts of up to 15% have been postponed five times since 2021, but are set to resume on Jan. 1, 2027. For the first time since 2019, CMS has the authority to price lab tests using updated data for CDLTs that aren't ADLTs, following passage of the most recent spending bill in February (here). The spending bill did not adjust the annual reporting schedule for ADLTs.

- PAMA data collection of lab-reported pricing for CDLTs is ongoing, with data analysis and public meetings in the summer, proposed & finalized pay determinations in the Fall, and new rates effective Jan. 1, 2027 (timeline here).
- The current data reporting period is May 1, 2026 – July 31, 2026, and based on the updated data collection period of January 1, 2025 – June 30, 2025 (PAMA Reporting FAQ here).
- There's no phase-in reduction in 2026. Beginning January 1, 2027 – 2029, payment may not be reduced by more than 15% percent per year compared to the payment amount established for a test the preceding year.

Clinical labs continue to push the *RESULTS Act*, but it is unlikely to pass in 2026. The lab industry supported the most recent delay of PAMA cuts until 2027 and the implementation of more recent data reporting (here). However, the industry continues to push for passage of the *RESULTS Act to* provide a more favorable data reporting and rate-setting methodology and new limits for rate increases and decreases in future years. The bill would freeze CLFS rates at current levels through 2028 and cap reimbursement cuts at 5% per year beginning in 2029, with no cap on rate increases (our take here). Congressional activity around lab reimbursement will likely occur closer to year end along with other health extenders, but the outlook for the *RESULTS Act* will depend on cost. There is no CBO score yet for the *RESULTS Act,* which we assume means there is a score (and one that would require an offset for bill passage).

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