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COMPLIANCE & POLICY REPORT

Compliance and Regulatory Analysis for Lab Directors and Managers

Medicare's MolDX Working to Streamline Policies, Speed Assessments

Medicare's Molecular Diagnostics (MolDX) program was developed in 2011 to identify and establish coverage and reimbursement for molecular tests. The program has agreements with four Medicare administrative contractors (Palmetto GBA, Noridian Healthcare Solutions, WPS Government Health Administrators and CGS Administrators) that cover 28 states. Palmetto administers the program. *LE Compliance & Policy Report* recently spoke to Gabriel Bien-Willner, MD, PhD, chief medical officer at MolDX, about developments in the program. See the full interview on pages 2-4.

Top Compliance Challenges for Clinical Laboratories

L*E Compliance & Policy Report* recently spoke with David Gee and Caitlin Forsyth, attorneys with Davis Wright Tremaine, about compliance challenges clinical laboratories are facing. Gee is a partner in the firm's Seattle office. Forsyth is counsel in the firm's Portland office.

Medical necessity, especially in regard to urine drug testing and Covid testing, continues to present serious challenges for labs. Marketing in the toxicology space also is a focus of government agencies. Details on page 7.

Payment, Coverage Key Policy Concerns for MAWD Pathology

Payment and coverage for molecular diagnostic tests top the list of worries that keep Natasha Villanueva, MHA, MLS(ASCP)CM, Vice President of Clinical Laboratory for MAWD Pathology Group (Lenexa, KS), up at night.

"I am concerned about all of the evolving policies surrounding molecular diagnostics," Villanueva tells *LECPR*. "It is difficult to keep up with all of the different payer policies. Some of the policies are too vague, and many keep evolving. It feels like the goal posts are always moving." Continued on page 5.

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Welcome to the first issue of Laboratory Economics Compliance & Policy Report. Each month we will bring you in-depth interviews with policymakers, attorneys, lab compliance officers and others, along with insight into the latest compliance, regulatory and policy developments affecting clinical and anatomic pathology laboratories. Interested in subscribing? Details on page 12. Kimberly Scott, Editor

To Get the Full Issue, Subscribe to **Laboratory Economics Compliance & Policy Report!**

Laboratory Economics Compliance & Policy Report is a monthly business newsletter that delivers critical information regarding developments in laboratory law, regulations and compliance. Our editors talk to attorneys, payers, lab compliance officers and other experts to find out what you need to know to ensure your lab stays in compliance with key state and federal policies. These insights could save you thousands of dollars in potential fines, penalties and attorney's fees. Subscribe today, and you will immediately receive a PDF file of the current issue. Then, every month you'll receive 12 pages filled with insight into how to minimize your laboratory's compliance risk.

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- Keep up to date on federal policy developments affecting clinical and anatomic pathology laboratories, including oversight of lab-developed tests, reporting requirements under PAMA, changes to CLIA and revisions to medical necessity policies.
- Hear about important updates regarding the False Claims Act (FCA), the Physician Self-Referral Law (Stark Law), the Anti-Kickback Statute (AKS), the Eliminating Kickbacks in Recovery Act (EKRA), the Civil Monetary Penalties Law (CMPL) and the Exclusion Statute.
- Get in-depth interviews with payers about how coverage and reimbursement decisions are made and what you can do to have a say in decision-making.
- Hear directly from health care attorneys about trouble spots for labs and tips on how to ensure your lab remains in compliance with federal and state laws.
- Learn from fellow laboratory executives and compliance officers about what keeps them up at night and steps they are taking to ensure compliance and minimize risk.
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