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Beyond COVID-19: The 6 Hottest Lab Compliance Stories Almost Nobody Is Paying Attention To

If not burnout, you may be suffering from a case of COVID-19 fatigue right now. And you're not alone. The monster virus has seemingly consumed everything in its path over the past six months, including the world's attention. While completely understandable, the current fixation on COVID-19 belies the fact that there are other important developments taking place that may directly affect your lab. So, as we move into the second half of 2020, let's step back and recognize the year's biggest non-COVID-19 stories in lab compliance that have flown under the radar due to the pandemic.

1. The Continuing Crackdown on Urine Drug Testing

Before the pandemic, the opioid crisis was the primary driver of health care fraud and abuse enforcement activity. COVID-19 has done little to alleviate either the opioid problem or level of pressure

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Compliance Alert: OIG Targets COVID-19 Test Labs for Potential Add-on Testing Abuses

Are labs taking advantage of the unprecedented demand for COVID-19 testing to bill Medicare for high reimbursing and medically unnecessary add-on tests? That's what the OIG suspects and it plans to conduct an investigation to confirm its suspicions.

The Potential for COVID-19 Add-on Testing Abuse

The objective of COVID-19 testing is to determine whether an individual has the virus. However, as the OIG points out in its latest work plan addition, labs can also perform add-on tests, e.g., to confirm or rule a diagnosis other than COVID-19. In the new work plan item expresses, the agency says it has "program integrity concerns" related to add-on tests in conjunction with COVID-19,

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enforcers are exerting against labs and other providers involved in opioid-related testing scams, most of them for billing Medicare and Medicaid for medically unnecessary drug tests. Since April 24, there have been at least five high profile settlements or convictions announced, as summarized by the Scorecard below:

Scorecard:
Recent Medically Unnecessary Drug Testing Enforcement Actions

Status of Case	Accusations
Operators of American Toxicology Labs (Virginia) plead guilty to fraud + await sentencing	Excluded provider opens and runs a lab that generates $8.5 million in billings for urine screens for entities representing themselves to be opioid treatment facilities
Co-founder of Liberation Way drug and alcohol rehab clinic in Pennsylvania sentenced to 37 months' prison + $3.1 million in restitution for health fraud conspiracy*	Defendant ran an overbilling and elaborate kickback scheme involving thousands of medically unnecessary urine tests sent to Florida-based labs for analysis
Physician owner of Seattle Pain Center + Northwest Analytics testing lab pays $2.85 million to settle false claims charges	Clinics required all patients to undergo urine drug screening, generating thousands of medically unnecessary tests performed by the lab and then billed to Medicare + Medicaid
Connecticut Counseling Centers pays $295K to settle claims of overbilling Medicaid for outpatient substance abuse services	Methadone clinic billed Medicaid for urine drug tests even though reimbursement for those services were included as part of its bundled weekly payment rate
Logan Laboratories and Tampa Pain Relief Centers, Inc. + two executives pay $535,449 to settle claims of falsely billing Medicaid for medically unnecessary urine drug tests	Defendants automatically ordered both presumptive and definitive urine drug testing for all patients at every visit, without having a physician determine that the testing was medically necessary for those particular patients
Lab owner sentenced	Owner of Florida lab separately sentenced to 15 months' prison and $3.4 million in restitution for his part in scheme

2. The Continuing Crackdown on Genetic Testing Consumer Scams

Consumer scams involving genetic testing labs (CGx) continue to represent perhaps the fastest-growing segment of the federal enforcement industry, probably because they target the most vulnerable. Far from slowing the momentum, the pandemic is actually fueling the scammers by creating new opportunities for SARS-CoV-2 testing schemes.

Under the typical *modus operandi*, "recruiters" contact Medicare beneficiaries online, on the phone or face-to-face at health fairs, senior centers, low-income housing areas or religious institutions like

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churches and synagogues promising free genetic testing to determine the individual's cancer risks and how they'd respond to certain drugs in exchange for a cheek swab, personal Medicare information and a copy of their driver's license. Next, the scammers contact the beneficiaries' doctors and ask them to order the tests in return for a cut of the Medicare payment. Even if the doctor refuses, the scammers can count on the cadre of doctors they've lined up who are willing to prescribe the tests without seeing or making a determination of whether those tests are medically necessary.

The enforcement momentum that began in 2019 with the nationwide "Operation Double Helix" takedown has continued into 2020. Consider the following cases, all of which came down since June:

- **July 9:** Pennsylvania U.S. Attorney indicts seven people for role in massive CGx scam in which physicians were paid kickbacks of $5,000 to order more than $2 million worth of medically unnecessary CGx tests;
- **July 1:** California-based molecular testing firm Agendia, Inc. pays $8.25 million to settle charges of running a nationwide scheme to falsely bill Medicare for its flagship MammaPrint genetic test for predicting breast cancer recurrence risk;
- **June 5:** The operator of recruiting firm Privy Health Inc. pled guilty to conspiring with a Florida lab network and ordering physician to bill Medicare for nearly $5 million in CGx tests without regard to medical necessity and will be sentenced in October; and
- **June 3:** Owners of labs in Texas and Mississippi admitted their roles in a scheme to pay kickbacks in exchange for referrals of patient DNA samples for genetic testing and are awaiting sentencing.

3. Labs Get Some PAMA Relief for 2021

For labs, the headline of the $2 trillion federal COVID-19 relief bill, aka, CARES (Coronavirus Aid, Relief and Economic Security Act), was free coronavirus testing for patients without adequate financial assistance for the testing lab. What went largely unnoticed in the legislation was the relief it provides on PAMA Medicare Part B lab test price cuts. Explanation: The original plan was for the reduction cap, i.e., maximum amount by which CMS could reimburse for Medicare Part B lab tests, was scheduled to rise to 15% in 2021. But CARES puts the cap rise and resulting reimbursement cuts on hold for one year. And given how the political tide had been turning in the lab industry's favor before the COVID-19 crisis, that extra year may prove extremely valuable down the road.

4. New DOJ Guidance on Self-Disclosure

As the year began, the DOJ issued new guidance on how labs and other

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providers who discover internal False Claim Act (FCA) violations have occurred within their organization can come forward, confess and ensure maximum leniency from regulators. More precisely, the new Justice Manual guidance outlines clear criteria and specific examples of actions they can take to earn credit for:

- Voluntary disclosure of FCA violations;
- Cooperating with the investigation; and
- Implementing remedial measures to correct and prevent recurrence of identified problems.

5. FDA Issues Guidance on Oncology Drug CDx Labeling

In April, the FDA issued new guidance on an important issue it has been historically reluctant to address: labeling of companion diagnostics (CDx) for personalized cancer therapies. Specifically, the guidance explains how CDx developers can broaden the indication for a test so that it references a group of similar drugs rather than a specific treatment. In addition to providing oncologists greater flexibility, the agency acknowledges that labeling companion tests more broadly would reduce the regulatory burden for labs and enhance the utility of the test.

Test developers will need hard evidence to support broader labeling; simply matching diagnostic and therapeutic targets won't be enough, according to the guidance. "Different diagnostics for the same target may utilize different cut-offs, filters, or other design features that impact the patient populations they identify and, consequently, the likelihood of a biomarker-positive patient to respond to a given therapy," the agency notes. "Any potential differences should be evaluated to ensure it is clinically appropriate to take a broader labeling approach."

6. Surge in Healthcare Worker Fatalities

One of the most overlooked consequences of the pandemic has been the exponential increase in fatalities and catastrophic injuries among healthcare workers. According to an analysis from *Modern Healthcare*, of the 202 workplace investigations performed by federal and state OSHA at hospitals, nursing homes, doctors' offices, home health agencies and rehabilitation centers in April 2020, more than 130 were for a fatality or catastrophic injury, up more than 4,300%(!) from April 2019 when only three out of 117 investigations involved a fatality or catastrophe.

While the investigation reports don't specify the cause, labor attorneys interviewed by *Modern Healthcare* suggest that COVID-19 is almost surely the cause of this alarming spike. In addition to taking down healthcare workers, the virus is wreaking havoc on maintenance and other workers who work at health facilities.

Takeaway

There's more to lab compliance than COVID-19. Pre-existing enforcement trends like the crackdown on urine drug and CDx testing have not only continued but also gained momentum during the pandemic. In addition, pandemic politics, economics and working conditions are having significant impacts, some positive but most negative, that have largely gone unrecognized.

FDA WATCH

FDA Provides New Guidance on Validation of Sample Pooling for SARS-CoV-2 Test Development

On June 16, the FDA issued new guidance to help labs and commercial manufacturers use test sample pooling to develop, validate and acquire Emergency Use Authorization (EUA) of qPCR-based SARS-CoV-2 detection tests.

Pooling & SARS-CoV-2 Test Development

Pooling is a technique that involves mixing aliquots, i.e., sub-samples extracted from individual samples into a pool or "batch" that can be tested with a single test. If the entire pool returns a positive result, the individual samples are retested to locate the source of the positive; if the batch tests negative, all of the constituent samples are also deemed to be negative.

Historically, developers of EUA tests have used pooling to modify how those tests are used. In the context of the current pandemic, pooling offers the advantage of conserving testing resources that have been in short supply. During her June 23 keynote address to the American Society for Microbiology Microbe conference, White House coronavirus task force response coordinator Deborah Birx called on labs to make greater use of pooling, suggesting that the technique "would give us the capacity to go from a half a million tests per day to potentially 5 million individuals tested per day."

However, there's also a downside of pooling to the extent that it dilutes the nucleic acids produced by the SARS-CoV-2 virus, creating the risk of false negatives. As a result, test producers who use pooling must account for the false negative effect in validating the modified use.

The New Guidance

The new FDA guidance, which takes the form of additions and revisions to the pre-existing EUA templates for laboratory developed tests

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FDA Watch: FDA Provides New Guidance on Validation of Sample Pooling for SARS-CoV-2 Test Development, *from page 5*

(LDTs) and molecular diagnostic tests, outlines the agency's "validation expectations" for the use of specimen pooling either to develop a new test for EUA or modify the use of one that has already received EUA clearance. Specifically, it recommends use of a Dorfman or simple pooling approach combining samples into non-overlapping pools and testing each sample pool.

The utility of pooling to scale up testing depends on prevalence, test sensitivity and the number of low-positive samples. The dilution of samples used in pooling may reduce sensitivity. Result: Positive cases may go undetected, particularly weakly-positives in which viral concentration may already be near the limit of detection.

Validation of Pooling

According to the template, a pool of five samples is a reasonable starting point for validation of pooling for a high-sensitivity test in populations with a positivity rate of approximately 5 percent to 6 percent; however, the agency suggests that smaller pools may be necessary in populations with higher prevalence rates.

The FDA suggests that labs and developers test a random sampling of patient samples without pooling to evaluate the positivity rate and percent of weak positive samples in the testing population and to identify differences in positivity rate between those tested individually and those tested through pooling.

To validate pooled testing, labs and developers should characterize the reduction in assay analytical sensitivity indicated by a shift in Ct score for RT-PCR assays with respect to the number of samples to be pooled to ensure the selected sample pooling strategy maintains appropriate sensitivity. They should also determine the maximum number of samples acceptable to pool for each specimen type.

The FDA recommends conducting a clinical validation study in the intended use population that includes testing each sample individually and using the proposed pooling strategy.

For validation, a clinical study of a five-sample pool strategy should include at least 20 individual positive samples and 180 negative samples, either archived samples or freshly collected. The study should compare the performance of the EUA-authorized assay when testing single specimens to the performance of the assay when testing sample pools.

Adding pooling to a test that already has EUA requires a clinical study large enough to include 20 positive samples. Labs and developers should submit an EUA amendment request with the appropriate validation data, but don't have to establish assay performance with a separate comparator test.

The Template for Developers

The FDA strongly encourages developers to "work with their customers to gather existing data." **Example:** 100 Ct scores from individually tested positive patient samples can be used to evaluate the percentage of samples with Ct scores close to the assay Limit of Detection (LoD), or weak positives.

A Ct shift of Log2(n), where "n" is the number of samples in a pool, can be estimated, e.g., so that a Ct shift of 2.3 is expected such that for a pool of five samples. According to the template. "Therefore, if a large percentage of positive patient samples are close to your assay LoD, you may want to consider a smaller n, which will reduce the observed Ct shift and maintain higher sensitivity." The template recommends that at least 25 percent of the validation samples be within 2-3 Ct of the cut off, and no more than within 2-4 Ct.

For an LDT or commercial test that's not previously authorized, pooling can be included in the EUA filing, but must also include performance characterization with a high-sensitivity comparator assay and a clinical study of pooling involving at least 30 individual positive samples and enough negative samples to generate 30 five-sample pools with one positive sample plus 30 five-sample pools with only negative samples.

Takeaway

Use of specimen pooling for purposes of developing new lab tests and expanding the use of previously approved ones is nothing new, of course. Historically, while the FDA "has encouraged all test developers to reach out to the agency to discuss appropriate validation approaches," it hasn't made any specific recommendations on the subject. So, the decision to add guidance on specimen pooling to its template is a significant policy change, which an agency statement describes as a "step forward. . . to help facilitate the preparation, submission, and authorization under an" EUA. In the larger context, the move represents a continuation of the FDA's strategy of backing away from its initial laissez faire approach to COVID-19 testing quality in favor of a more active regulatory strategy.

FDA WATCH

FDA Warns of False-Positives from Becton Dickinson SARS-CoV-2 Test & Reagents

July 6 was a tough day for Becton Dickinson (BD) when the FDA issued a warning letter alerting clinical lab staff and providers of the increased risk of false-positive results from the New Jersey-based firm's BD SARS-CoV-2 reagents for its BD Max System test.

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FDA Watch: FDA Warns of False-Positives from Becton Dickinson SARS-CoV-2 Test & Reagents, *from page 7*

The Warning Letter

If you're using the reagents for the BD Max System and get a positive result, you should treat the result as presumptive and consider confirming the result with another authorized test, the agency recommends. The warning letter also calls on lab staff and providers to report any issues with using COVID-19 tests.

The FDA granted Emergency Use Authorization (EUA) for the BD PCR-based SARS-CoV-2 kit on April 8. The test, which detects viral nucleic acid from SARS-CoV-2 in upper respiratory specimens, was cleared for moderate- and high-complexity testing labs on the BD Max System using BD reagents. However, the company began receiving reports of the potential for false positives when the test was used with the reagents, including one study in which a manufacturer found that approximately 3 percent of results were false positives.

Even though the users citing accuracy concerns represented a small subset of overall true-positive results, the firm approached the FDA to discuss the problems and options to improve test performance, according to a BD spokesperson. The FDA is currently working with the firm to resolve the issue and promises to provide new or additional information as the situation develops.

Takeaway

Accuracy and the risk of false positives generated by EUA COVID-19 serology tests has been an ongoing concern. However, the BD test is a molecular PCR-based assay which are generally considered more accurate and reliable than serology-based antibody tests. Even so, the BD situation seems to be a bit of an outlier limited to a particular PCR product using a particular reagent on a particular platform.

Inside the Beltway: President Calls for Cutting NIH Budget but Congress Increases It Instead

The Trump administration wanted to slash the National Institutes of Health (NIH) budget but Congress wouldn't allow it. It's been the same narrative for the past four years. But even though it's dog-bites-man, rather than the other way around, the story is still noteworthy, especially in times of pandemic.

The Budget Back-and-Forth

This year's version of the pas de deux began in February when the

President proposed reducing the NIH's budget roughly 8 percent from $41.46 to $38 billion.

The President's FY 2021 NIH Budget Proposal

NIH Institute (not inclusive)	FY 2020	Proposed FY 2021
National Cancer Institute	$6.44 billion	$5.69 billion
National Human Genome Research Institute	$606.3 million	$550.1 million
National Institute of Allergy and Infectious Diseases	$5.89 billion	$5.45 billion
Total	$41.46 billion	$38 billion

Of course, all of this was before the pandemic. Still, as usual, Congressional Republicans and Democrats declined the proposed cuts and increased the NIH budget instead. And that's where things are headed this year. Thus, on July 14, the U.S. House of Representatives Appropriations Committee approved a $5.5 billion increase in NIH FY 2021 funding to $46.96 billion, with all institutes and centers getting a boost, including:

- National Cancer Institute funding would increase from $6.44 billion to $6.91 billion;
- National Heart, Lung and Blood Institute funding would increase from $3.62 billion to $3.89 billion;
- National Institute of Allergy and Infectious Diseases funding would go from $5.89 billion to $6.39 billion; and
- National Human Genome Research Institute funding would increase from $606.3 million to $650.5 million.

The proposed House budget would also include a $5 billion emergency fund to help cover shutdown, startup and other costs related to delays in research in 2020.

Takeaway

The same familiar pattern is also unfolding with regard to the US Centers for Disease Control and Prevention with the House committee rejecting the President's proposed FY 2021 budget reduction in favor of a 3 percent increase—from $7.75 billion to $7.98 billion, including an extra $9 billion in emergency appropriations.

Labs Letter to VP Pence: Strapped by COVID-19 Testing Supply Shortages, Labs Call on White House for Help

Reagent shortages and supply chain bottlenecks have stymied COVID-19 testing from the very beginning of the crisis. As those problems remain and tests provided slips further behind demand, a handful of the lab industry's most powerful representatives have decided to appeal directly to the White House for help.

The Letter to Pence

On July 8, a group of eight organizations representing U.S. labs sent a letter to Vice President **Mike Pence**, with copies to HHS Secretary **Alex Azar** and **Deborah Birx**, MD, Response Coordinator of the Coronavirus Task Force, urging the government to find remedies for supply chain obstacles to performing COVID-19 tests. The letter signatories include the:

- American Association of Bioanalysts;
- American Association for Clinical Chemistry;
- American Medical Technologists;
- American Society for Microbiology;
- Association of Public Health Laboratories;
- Association for Molecular Pathology;
- College of American Pathologists; and
- National Independent Laboratory Association.

"Our members are on the front lines responding to the public health crisis," the letter begins. Since COVID-19 testing began, "they have experienced significant difficulty acquiring the supplies—test kits, nasopharyngeal and mid-turbinate swabs, transport media, and personal protective equipment (PPE)—needed to perform COVID-19 testing." The letter notes that labs have even been getting faulty or unusable equipment, including swabs from the Strategic National Stockpile.

The Appeal for Help

Without proper testing supplies and PPE, labs will continue to struggle to meet the demand for COVID-19 testing and assistance in tracking its spread, according to the letter. The assistance requested is essentially information:

1. Supply Chain Contacts Information

First, the letter asks for a list of the names and contact information for individuals in each state who are overseeing the supply chain for testing supplies and PPE for the federal government. "Many of our members report that they are unable to identify or initiate contact with these individuals," the letter explains.

2. Transparency of the Supply Allocation Process

The other request is "visibility into the process of supply allocation, demonstrating that the supplies being distributed at the state level are being allocated in a way that reflects the greatest need to effectively address COVID-19 in the U.S." According to the letter, labs need to understand in real-time, resource availability and reagent and supply quantities for planning purposes. The federal government should take a leading role in increasing transparency about the availability of these materials from both government and commercial manufacturers.

Takeaway

As the supply chain situation becomes more desperate, testing labs and other stakeholders are stepping forward to sound the alarm. At the end of May, the Association for Molecular Pathology (AMP), one of the letter's signatories, published a survey finding that more than 70% of U.S. labs have suffered significant COVID-19 testing delays as a result of supply chain disruptions. The AMP called on the Trump administration and producers of reagents and other testing supplies to furnish labs real-time updates on the availability of testing materials.

Last month, governors from Michigan, Colorado and Arkansas (two Democrats and a Republican, respectively) criticized the administration for failing to coordinate the procurement and distribution of COVID-19 testing supplies, which they claim is hindering the ramp up of critically needed testing.

Reimbursement: Not Making Insurers Pay for Back-to-Work COVID-19 Testing May Leave Labs Holding the Bag

Who should pay for desperately needed COVID-19 testing? In the first stage of the public health crisis, the federal government's answer was that insurers should pay the bills and not pass along the costs to patients. But now the administration is backing away from that policy by indicating that insurers don't have to pay for COVID-19 return-to-work testing of employees provided by employers as a preventive infection control measure. And if insurers aren't on the hook, labs that furnish the tests could end up footing the bill. Here's a rundown of the situation.

FFCRA Rules for COVID-19 Test Payment

The Families First Coronavirus Response Act (FFCRA) required insurers to cover COVID-19 tests without imposing any copayments, deductibles,

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coinsurance or other patient cost-sharing. But the rule (Section 6001 of FFCRA) rule applied only to tests deemed "medically appropriate" by a healthcare provider. The key question: Would insurers also have sole responsibility for employer screening tests not used for diagnosis and treatment?

On June 23, we learned that the apparent answer is NO when the Departments of Labor, HHS and Treasury issued joint guidance (FAQ 5) clarifying that Section 6001 doesn't apply to "testing conducted to screen for general workplace health and safety (such as employee "return to work" programs, for public surveillance or any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19."

Congressional Democrats Ask Administration to Change Its Mind

On July 7, Democratic leaders of key House and Senate health committees sent a letter asking the Trump administration to revise its policy. Exempting insurers from paying for return-to-work COVID-19 testing violates the clear free testing intent of the FFCRA legislation. "It is unacceptable that this Administration's priority seems to be giving insurance company loopholes instead of getting people the free testing they need," the letter contends.

Whether the letter is right or wrong, the fact that it was signed only by Democrats will limit its actual influence.

Takeaway: Significance for Labs

So, if insurers aren't on the hook, the consumers, i.e., employers will have to pay for return to work screening. Of course, this may discourage many employers from offering such testing in the first place—other than employers in skilled nursing and other high-risk facilities in which screening testing is mandated by state or local law.

*As with the original Section 6001 rule, labs may once more get caught in the middle and end up having to pay at least some of the cost. "While there is widespread agreement that this testing is necessary, the issue of how these tests will be paid for remains unclear," American Clinical Laboratories Association President **Julie Khani** in a written statement. "Laboratories cannot—and should not be expected to—absorb the costs for return to work and surveillance testing."*

The good news is that the issue is likely to be revisited now that the administration and Congress are gearing up to adopt a new round of COVID-19 relief legislation that will probably address payment of return-to-work COVID-19 testing.

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particularly the potential of fraudulent billing for associated respiratory pathogen panel (RPP) tests, allergy tests or genetic tests.

Adding to the concern is the fact that during the public health emergency CMS has relaxed the rules requiring an order from the treating physician or nonphysician practitioner (NPP) for COVID-19 tests. And, according to the OIG, relaxation of physician ordering/NPP rules gives "unscrupulous actors more leeway for fraudulent billing of unnecessary add-on testing."

The OIG Game Plan

To address these concerns, the OIG plans to perform a study analyzing Medicare claims data for lab testing to identify trends in the use of RPP, allergy and genetic testing and identify billing patterns indicating that labs may be committing fraud and abuse.

Takeaway

If your lab is performing add-on tests in conjunction with COVID-19 testing, be sure that you have clear and complete records documenting that those tests are medically necessary for the particular patient.

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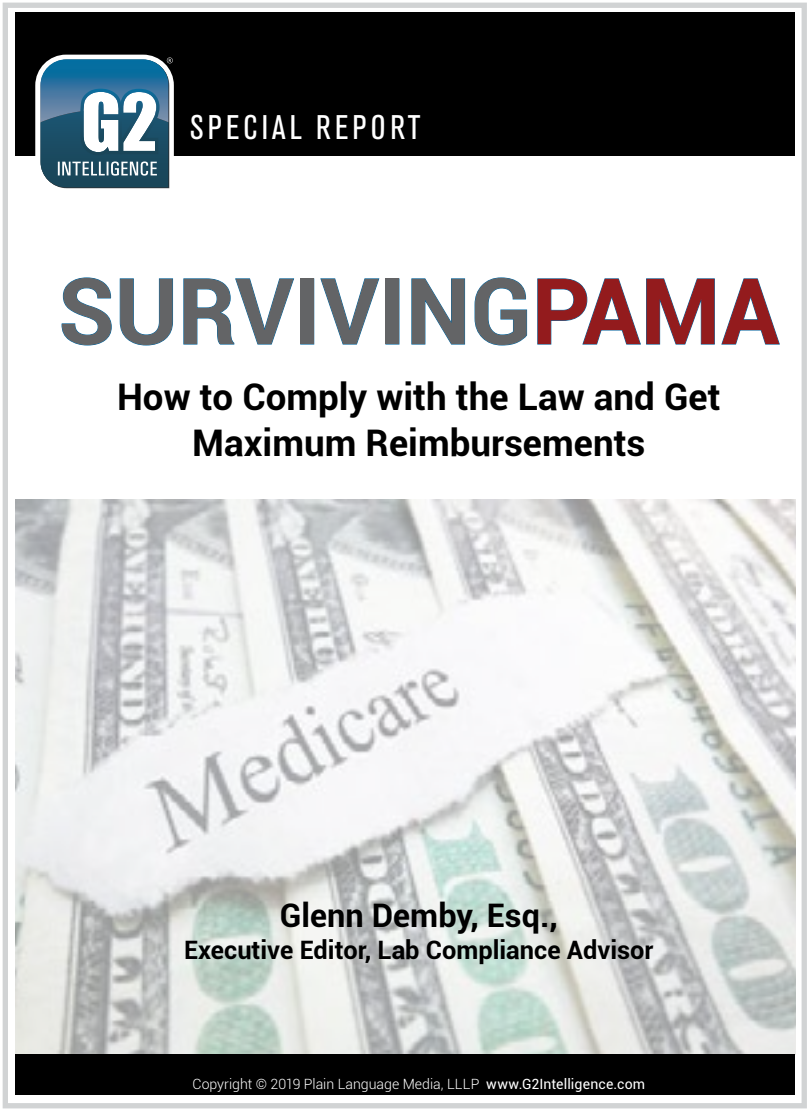

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