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LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

July 2019

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Compliance Perspectives: Use New DOJ Criteria to Vet the Effectiveness of Your Lab Compliance Program

One of the primary responsibilities of a lab manager is to ensure that the lab's compliance program is effective. There's a lot on the line. Having an effective compliance program can help prevent violations that can get your lab into legal hot water; and if things do go wrong, it can keep the resulting penalties to a minimum and may even enable you to avoid penalties altogether. There's just one little problem. How do you know exactly what makes a compliance program "effective"?

Wouldn't it be nice if the government actually came out and told you what it wants from your compliance program? Well, guess what: they just did. It happened on April 30, when the DOJ issued new internal guidance that explains what makes a compliance program effective. And since they're the ones who make that determination in actual cases, you'd be well advised to go to school on what the guidance says. Specifically, you should use the criteria the DOJ lays out to vet your own compliance program. Here's how to do that.

Continued on page 2

Case of the Month: Feds Target Doctors Who Took Kickbacks from HDL

When it comes to breaking up lab kickback schemes, federal enforcers start with the lab that paid the kickbacks and then turn to the downstream providers that accepted them. This was the pattern in the Millennium Labs case. And now it seems to be playing out in the other lab kickback mega-scandal, the one involving Health Diagnostic Laboratory, Inc. (HDL).

The Millennium Case

The Millennium scam, the largest lab kickback scandal in history, featured free point-of-care testing cups given to physicians for urine drug test referrals. In 2015, Millennium settled by agreeing to pay $256 million. But the case was a long way from over as federal enforcers targeted the referring physicians and practices that accepted the free cups from

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COMPLIANCE PERSPECTIVES, *from page 1*

Why the Guidance Is So Important

The so called Evaluation of Corporate Compliance Programs (Guidance) summarizes how the DOJ will evaluate whether a lab had an effective compliance program at the time it committed an offense. This evaluation will directly affect the DOJ's decision on what to do about your case—bring charges, negotiate a plea deal, charge you a lighter penalty, require you to enter a corporate integrity agreement, etc. The Guidance actually lists the "fundamental questions" DOJ attorneys will ask when evaluating your compliance program to determine how hard to come down on your lab:

- Is the compliance program well designed?
- Is the program being applied effectively, i.e., earnestly and in good faith?
- Does the compliance program work in practice?

Using the Guidance to Vet Your Own Compliance Program

Bottom line on top: Just *having* a compliance program isn't enough; to win credit with the DOJ, you must be able to show that you actually execute it in both action and principle. Let's go through the four questions you should ask in vetting your own compliance program against this imperative:

1. Do You Have a "Culture of Compliance"?

Before getting into the compliance program document, take a step back and examine whether your lab has what the Guidance calls a "culture of compliance and ethics." The Guidance makes it clear that the "tone" for compliance must be set at the most upper levels of management and the board of directors. Leadership must communicate a high level of commitment to implementing such a culture of compliance from the top down. This includes the development of policies and procedures enforced by middle management and the education and training of staff. DOJ also warns that it will look to how senior leaders, through their words and actions, have encouraged or discouraged compliance.

2. Is Your Compliance Program "Well Designed"?

Next, make sure your compliance program contains all the elements the Guidance lists as essential to being "well-designed," including:

- A robust risk assessment process;
- Appropriate and updated policies and procedures;
- Tailored training and communications;
- A confidential reporting structure and investigation process; and
- The application of risk-based due diligence to its third-party relationships.

Additionally, DOJ emphasizes that comprehensive due diligence of any acquisition targets must be done warning that "flawed or undetected due

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Lab Compliance Advisor
(ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

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diligence can allow misconduct to continue at the target company."

3. Is Your Implementation Effective?

Effective implementation, the Guidance explains, requires that those charged with day-to-day oversight of the compliance program have appropriate autonomy and resources to act with adequate authority and stature. DOJ attorneys will look at the sufficiency of personnel and resources within the compliance function by evaluating whether those responsible for compliance have:

- Sufficient seniority within the organization;
- Sufficient staff and resources to effectively undertake the requisite auditing, documentation and analysis functions; and
- Autonomy from management and direct access to the board of directors or its audit committee.

Internal audit functions must be conducted "at a level sufficient to ensure their independence and accuracy." In addition, incentives should be established for compliance and disincentives for noncompliance. Disciplinary actions and incentives should be applied are fairly and consistently across its organization.

4. Does Your Compliance Program "Work in Practice"?

The DOJ will rely on the following factors to judge whether a compliance program works in practice:

- Whether there's continuous improvement, periodic testing and review of the program;
- The frequency of internal audits, testing and review;
- The timeliness and comprehensiveness of investigations of allegations or suspicions of misconduct;
- The documentation of any findings, including documentation of any disciplinary or remediation measures taken; and
- The extent to which a thoughtful root cause analysis of misconduct is conducted and whether there's a timely and appropriate method to address the root causes.

Takeaway: Don't Fall in Love with the Document

Although the writing is important, there's much more to a compliance program than the actual document. That's the upshot of the Guidance and it reiterates previous DOJ previously warnings against "paper compliance programs," meaning those not backed with adequate:

- *Staffing to audit, document and analyze compliance efforts; and*
- *Training and notification of employees about the compliance program and the lab's commitment to it.*

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CASE OF THE MONTH, *from page 3*

Millennium. Since September 2017, more than a dozen physicians have been charged resulting in settlements of over $2 million.

The HDL Case

The case against HDL and its lab business associate Singulex, Inc. began as a *qui tam* whistleblower lawsuit alleging payments of kickbacks disguised as processing fees of $10 to $17 per test to physicians in exchange for orders of medically unnecessary blood tests; then, by billing Medicare and TRICARE for tests provided under the arrangement, the labs violated the False Claims Act (FCA). In April 2015, the case settled with HDL agreeing to pay $47 million and Singulex $1.5 million. Both labs also entered into Corporate Integrity Agreements with the government.

Next on the hot seat were the corporate principles of each company. Rather than settle, HDL's former CEO and two high-ranking marketing officials decided to fight it out in court. The strategy backfired when a federal jury found all three jointly and severally liable for kickbacks and false claims violations and handed down a $114.1 million verdict. (See *National Intelligence Report (NIR)*, July 3, 2018).

The Next Phase of the HDL Case

Now it looks like it's the physicians' turn to be held to account. On May 20, a pair of physicians and their Missouri practice entered into a $96,880 settlement agreement for accepting "process and handling" payments related to blood collection services from HDL in exchange for referring patients for testing. It's a pretty good bet that there will be many more such settlements in the weeks and months ahead.

Compliance Heads Up: New Kickback Safe Harbors Rule Is Almost Ready

After months of promises, posturing and public consultation, the Department of Health and Human Services is getting ready to unveil a proposed rule to liberate labs and other providers from the burdens of the kickback laws by providing new safe harbors to the Anti-Kickback Statutes and new exceptions to the beneficiary inducement bans of the Civil Monetary Penalty statute to allow for coordinated care. On June 5, the proposal was sent to the White House Office of Management and Budget, the agency that reviews proposed new regulations before they're made public. Although OMB review is the final step before publication, it can also take months to complete. But the latest Trump Administration regulatory agenda projects that the proposed rule will be released in July 2019.

So, stay tuned and we'll break down the new rules for you as soon as they come out. Meanwhile, if you need a summary of the recent hearings and what's expected to be in the proposed rule, see *National Intelligence Report (NIR)*, March 25, 2019.

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New OIG Report Confirms that Labs Are Still on the Enforcement Radar

After a recent dip, OIG enforcement activity has seemingly rebounded, at least in terms of total recoveries. That's the basic punchline from the newly published OIG Semiannual Report to Congress (covering Oct. 1, 2018 through March 31, 2019). The other key takeaway is that while they are no longer the main focus of OIG enforcement activity, labs are still very much on the agency's radar. Here's what lab managers need to know about the report.

Enforcement Activities

Year over year, enforcement activities were basically flat. The one notable exception was the 57% increase in total recoveries, $2.3 billion vs. $1.46 billion in the corresponding period last year.

Metric	FY 2018	FY 2019
Total Recoveries	$1.46 Billion	$2.3 Billion
Criminal Actions	424	421
Civil Actions	349	331
Exclusions	1,588	1,293

Payments for Unnecessary Tests

As usual, labs figured prominently in initiatives targeting improper Medicare and Medicaid payments during the period. The Report cites the example of a case in California involving GenomeDx Biosciences, which entered in to a settlement agreement to resolve allegations that it improperly billed Medicare for genetic testing services from Sept. 1, 2015 through June 30, 2017. Specifically, the United States alleged that GenomeDx submitted claims for Decipher Prostate tests (its flagship service) that were not medically necessary. GenomeDx agreed to pay more than $1.9 million to resolve its alleged liability.

Kickbacks

Labs also come up in the OIG discussion of affirmative litigation cases under the Civil Monetary Penalties Law, namely the crackdown against physicians on the receiving end of the Millennium Laboratories kickback scheme. Explanation: In 2015, Millennium agreed to pay $256 million to settle claims of providing free point of care urine drug testing cups (POCT cups) to physicians in exchange for test referrals. In September 2017, the case entered a new phase when enforcers began targeting the downstream physicians who accepted the free cups. To date, OIG-initiated affirmative litigation actions against the physicians and practices has yielded over $2 million in total recoveries.

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NEW OIG REPORT CONFIRMS THAT LABS ARE STILL ON THE ENFORCEMENT RADAR *from page 5*

Takeaways

OIG semiannual reports are somewhat formulaic, and the details don't appear to change much from year to year—until you look closely. It's also helpful to compare findings to previous years.

For lab managers, this year's report suggests:

- *Federal enforcement activity remains consistent;*
- *Emphasis is on maximizing recovery efforts in terms of financial payoff;*
- *Individuals and small companies are still targets, especially when criminal activity also involves larger entities;*
- *The opioid crisis continues to get attention; but where labs were once a target, the focus now is largely on prescription drugs abuse and prevention; and*
- *Labs remain on OIG's enforcement radar.*

OIG Monthly Work Plan Review: June 2019

This month, there were seven new Work Plan items. Two of these, detailed below, may have implications for some labs.

Opioid Use in Medicare Part D in 2018

Issue: The opioid crisis remains a public health emergency. In 2017, 47,600 opioid-related overdose deaths occurred in the United States. Identifying patients who are at risk of overdose or abuse is key to addressing this crisis.

OIG Action: An OIG data brief will provide 2018 data on Part D spending for opioids, as well as on beneficiaries who received extreme amounts of opioids through Part D and those who appeared to be doctor shopping. It will also provide data on prescribers who ordered opioids for large numbers of these beneficiaries.

Opioid Use in Medicare Part D in Missouri in 2018

Issue: Drug overdose deaths are at epidemic levels, and the opioid crisis is a public health emergency. In 2017, there were 47,600 opioid-related overdose deaths in the United States; 952 of these deaths occurred in Missouri. Identifying beneficiaries who are at risk of overdose or abuse is key to addressing this crisis.

OIG Action: An OIG data brief will provide information on opioid use in Medicare Part D in Missouri in 2018, including data on beneficiaries who received opioids and data on beneficiaries who may be at serious risk of opioid misuse or overdose.

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Enforcement Trends: DOJ Changes to Yates Memo Make It Easier for Labs to Get Credit for Cooperating with Investigators

For the past five years, the DOJ has followed an enforcement policy designed to hold directors, officers and other top corporate officials responsible for the wrongdoing their companies commit. Last November, the agency announced some subtle but highly significant modifications to that policy, referred to as the "Yates Memo" after the document that inaugurated it. Bottom line on top: The DOJ is lowering the threshold that labs and other investigation targets must meet to receive cooperation credit in resolving investigations. Specifically, the agency is abandoning its previous "all or nothing" approach to cooperation. Here's an explanation of the change and what it may mean to you.

The Yates Memorandum

In September 2015, then Deputy Attorney General Sally Quillian Yates issued a memo calling on DOJ attorneys to bring charges against not just corporations that commit violations but also the individual leaders of the company who are responsible for those transgressions. (For more on the Yates Memo, see *Lab Compliance Insider (LCA)*, Feb. 22, 2017.) The memo represented a major shift in federal enforcement policy that had wide-ranging impact. The Yates Memo also outlines the procedures for prosecutors to follow in achieving that objective, including during the investigation phase of the case. Specifically, the Yates Memo provided:

- Healthcare and other entities should no longer qualify for leniency based on cooperating with law enforcement unless they provide the government "all relevant facts relating to the individuals responsible for the misconduct." (Translation: If a lab wants a break, it basically has to throw responsible lab officials under the bus.);
- Absent "extraordinary circumstances," DOJ settlements with healthcare and other entities should not release culpable individuals from civil or criminal liability when resolving a matter with an entity. (Translation: Lab officials must fend for themselves and can't piggyback on the lab's settlement agreement.);
- Civil suits for money damages should be brought against individual defendants without regard to their ability to pay. (Translation: Being broke and uninsured won't get lab officials off the hook.)

Pitting Labs against Their Leaders

In the aftermath of the Yates Memo's issuance, the DOJ has pressured healthcare and other entities to turn on their executives/directors/

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ENFORCEMENT TRENDS *from page 7*

managers in exchange for leniency. This included inserting into settlement agreements a "cooperation clause" requiring the settling entity to:

- Fully cooperate with investigations into the allegations covered in the settlement, including into "individuals and entities" that the settlement doesn't release from liability;
- Make "former directors, officers and employees available for interviews and testimony"; and
- Give the government non-privileged documents relating to the conduct covered in the settlement.

A Kinder, Gentler Cooperation Policy

During a November speech, Deputy Attorney General Rod Rosenstein acknowledged the shortcomings of this "all or nothing" approach. Expecting an entity to "admit the civil liability of *every* individual employee" involved in the wrongdoing to qualify for cooperation credit is "inefficient and pointless in practice," according to Rosenstein. Instead, entities will be expected to identify only those individuals who were "*substantially* involved in or responsible for the misconduct." To qualify for *any* cooperation credit in a civil case, entities now "must identify all wrongdoing by senior officials, including members of senior management or the board of directors."

Practical Impact

As Rosenstein acknowledged in his speech, the prior policy wasn't strictly followed in many cases because it would have impeded resolution and wasted resources. The new policy is thus just an acknowledgement of reality.

Labs still must "identify every individual who was substantially involved in or responsible for the criminal conduct" to receive cooperation credit. But they don't have to expend time and resources identifying and collecting information about individuals who aren't substantially involved in the misconduct and who are unlikely to be prosecuted.

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The new DOJ policy also gives more discretion to prosecutors in civil cases, specifically, discretion to accept settlements that remedy the harm and deter future violations, as well as to offer partial cooperation credit to corporations.

The DOJ policy change means that labs can focus on addressing the misconduct at issue and limit their focus to the key employees who were responsible. Under the new policy, labs can also earn cooperation credit even when they can't provide evidence on all relevant individual wrongdoers, whether for legal reasons or because they "genuinely cannot get access to certain evidence." Caveat: To get credit in these situations, the lab must be able to adequately explain the impediments and restrictions to DOJ.

Takeaway: Shielding Top Officials Is Still Not an Option

Be careful not to interpret these policy changes as meaning you can protect lab executives and employees who are responsible for wrongdoing. The new policy makes it clear that DOJ attorneys may refuse to award cooperation credit "to any corporation that conceals misconduct by members of senior management or the board of directors, or otherwise demonstrates a lack of good faith in its representations."

Trap to Avoid: Asking Lab Employees about Their Latex Allergies

"Are you allergic to latex?"

It seems like a perfectly legitimate thing to ask, especially to an employee who's expected to wear latex gloves on the job. The problem is that asking the question may expose you to risk of liability under the Americans with Disabilities Act (ADA).

The Risk

The ADA bans employers from discriminating against individuals with disabilities. EEOC guidelines make it clear that directly asking employees or job applicants if *they have* a disability is a form of illegal discrimination. Latex and other specific allergies are considered a "disability" under the ADA. Result: You're not allowed to ask employees and job applicants if they're allergic to latex.

How to Prevent It

What *you are* allowed to ask a lab employee or job applicant required to wear latex gloves is the following question: "Do you have any allergies or other conditions that would prevent you from carrying out the essential functions of the job?" This question is okay for two reasons:

- It doesn't ask about latex allergies or any other specific disability; and
- It addresses the person's capacity to do the job, rather than his/her physical or mental condition.

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Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

IBM Shells Out $14.8 Million to Settle Claims of Overselling ACA Software

Case: The DOJ contends that IBM and Cúram Software, the company it acquired in 2011, misrepresented the capabilities of its products to win a subcontract to develop an Affordable Care Act health insurance exchange website and information technology platform for the Maryland Health Benefit Exchange in February 2012. The alleged claims were made during a product presentation one month earlier demonstrating the software's capability to calculate tax credits and integrate with another subcontractor's health plan shopping software. The claims proved unfounded and, after a series of mishaps with the product, the Maryland Health Benefit Exchange terminated the contract in October 2013.

Significance: The Maryland health insurance exchange rollout proved a disaster and IBM, as the provider of the technology, is being blamed for the problems. Of course, several other states experienced significant health insurance exchange website failures, but the Maryland case was particularly high profile due in part to the parties involved including not only IBM but also then Governor Martin O'Malley and Lt. Governor Anthony Brown, who were running for President and Governor, respectively. Each man would go on to lose his election bid due in part to the negative publicity from the exchange fiasco.

CMS Finds Lab Safety Violations at Texas Hospital

Case: CMS has found the University of Texas MD Anderson Cancer Center out of compliance with Medicare conditions of participation with regard to lab services. The inquiry began in December 2018 after MD Anderson reported an adverse event related to a blood transfusion to the FDA, which then referred the case to CMS for a separate investigation. Although the details haven't yet been made public, CMS has apparently required the lab to submit a plan for remedying the problems by June 18.

Significance: Although the lab deficiencies were the only ones requiring a corrective action plan, CMS reportedly uncovered other conditions of

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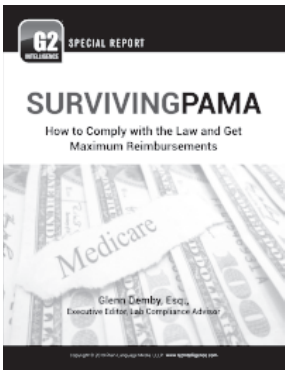

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participation violations involving MD Anderson's governing body, quality assessment and performance improvement program and patient rights. CMS hasn't threatened to revoke its Medicare status but MD Anderson will be subject to Texas health department investigation to ensure it complies with the conditions.

Florida Doctor Settles Kickback, False Claims Charges for $911K

Case: A Florida doctor settled charges of taking kickbacks for referring patients to Universal Oral Fluid Laboratories, a now-defunct drug testing lab in Pennsylvania, and then causing claims to be submitted to Medicare for the tests. In addition to shelling out a $911K fine, the doctor had to sign a corporate integrity subjecting his practice's billing operations to government review for three years.

Significance: This isn't the first doctor accused of receiving improper payments from Universal. In May, three other physicians pleaded guilty to similar charges for allegedly carrying out a conspiracy involving enabling the lab to generate millions in improper Medicare and Medicaid billings. The settlement amounts, respectively, were $370K, $200K and $130K. Universal's owner has also been indicted for his role in the scheme.

Kentucky Lab Settles Self-Disclosed SVT False Billing for $88.2K

Case: Commonwealth Pain Associates became the fifth urine drug test provider to settle with the OIG for self-disclosed billing of specimen validity tests (SVT). The price tag: $88,215. Although Medicare covers urine drug testing for managing medical treatment, it deems SVT not medically necessary where its sole purpose is to verify that a specimen is unadulterated.

Significance: In February 2018, the OIG issued a report saying that Medicare made $66.3 million in improper SVT payments to nearly 4,500 labs and physician offices. CMS has ordered Medicare contractors to recover those payments. Meanwhile, labs are proactively coming forward to self-disclose. There have been five settlements since the start of 2019, all involving providers from the Ohio Valley area, generating over $500K in total recoveries:

Date	Lab	Settlement Amount
Jan. 24	Northern Kentucky Center for Pain Releif	$126,799
Feb. 6	Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD (Ohio)	$111,706
March 13	VerraLab JA, LLC (Louisville, KY)	$125,983
March 13	Medical Specialist of Kentuckiana, PLLC (Louisville, KY)	$69,776
May 30	Commonwealth Pain Associates, PLLC (Louisville, KY)	$88,214

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LABS IN COURT, *From Page 11*

Feds Charge Pain Clinic Owner with Running Urine Drug Testing Scam

Case: A South Carolina chiropractor has been indicted for using the pain management clinics and drug testing labs he owned to bilk government and private insurers. According to the complaint, from 2011 to 2018, the chiropractor and his clinics:

- Paid physicians and other providers kickbacks based directly on the volume of referrals they made to the labs;
- Entered into "direct bill" agreements under which providers were allowed to pay the labs a set fee for test panels and then bill private insurers directly for the tests, usually at an amount above the set fee;
- Directed or encouraged providers to use "standing orders" of lab tests for all or most of their patients regardless of their individual needs; and
- Billed Medicare, Medicaid and TRICARE for medically unnecessary steroid injections and opioid prescriptions.

Significance: The case began as a whistleblower lawsuit brought by former clinic employees claiming that the clinic's 20 doctors saw about 75 patients per day, most of them on Medicare and Medicaid, generating daily billings in excess of $592K. But according to the whistleblowers, the group's biggest money maker was opioid prescriptions, which were allegedly dispensed like Tylenol, and accompanied by urine drug testing.

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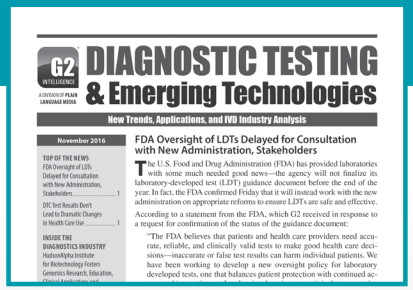
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