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INSIDE THIS ISSUE

Compliance: DOJ Explains What It Wants from a Compliance Program

While it may not prevent all violations, the right compliance program can help your lab get lighter penalties if things go wrong. But what exactly is "the right compliance program." On April 30, the DOJ issued new internal guidance that goes a long way in answering that question. **Bottom line on top:** Just having a compliance program isn't enough; to win credit, you must be able to show that you actually execute it in both action and principle.

What's At Stake

The 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 lists the "fundamental questions" DOJ attorneys will

Continued on page 2

FDA Watch: Agency Okays Marketing of Zika Test for First Time

Over the past several years, the FDA has issued Emergency Use Authorization (EUA) for over a dozen different tests for Zika. But on May 23, 2019, the FDA did something it had never done before: It authorized *marketing* of a diagnostic test for the Zika virus—specifically, Seattle-based InBios' ZIKV Detect 2.0 IgM Capture Elisa for detecting immunoglobulin (IgM) antibodies in human blood, an assay previously cleared for emergency use only. Here's the lowdown on the approval and its significance.

The Context: About Zika

The Zika virus is spread to people primarily through the bite of an infected

Continued on page 10

Compliance: DOJ Explains What It Wants from a Compliance Program, *from page 1*

ask when evaluating your compliance program:

- 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

The Guidance is a godsend because it enables you to evaluate whether your lab's own compliance program would meet DOJ standards. Let's go through the four questions you should ask in doing your vetting.

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 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

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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," i.e., 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.*

Compliance: 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.

Continued on page 4

Compliance: New OIG Report Confirms that Labs Are Still on the Enforcement Radar, *from page 3*

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.

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.

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.

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.*

Genetic Testing: OIG Issues Genetic Testing Fraud Alert

On June 3, the OIG issued a fraud alert warning of a genetic testing fraud scheme. According to the OIG, scammers are using telemarketing calls, booths at health fairs and public events and door-to-door visits offering Medicare beneficiaries cheek swabs for genetic testing. The objective is to get beneficiaries to reveal their Medicare information and use that information for fraudulent billing and/or identity theft. If the beneficiary agrees to genetic testing or verifies personal or Medicare information, a testing kit is sent even if it's not ordered by a physician or medically necessary. The fraud alert lists the things beneficiaries can do to protect themselves, including:

- Not accepting a genetic testing kit mailed to them unless their physician ordered it;
- Keeping a record of the sender's name and the date you returned the items; and
- Being suspicious of anyone who offers them free genetic testing and then requests their Medicare number.

Case of the Month: Physicians Come Under Fire for Taking Blood Processing Fee Kickbacks from HDL

Like the tango, it takes two to break the anti-kickback laws: one to offer and pay the kickback and the other to accept it. When a major scheme involving payment of kickbacks for lab testing referrals is broken up, the lab, the lab that made the payments is the primary target. But once the lab is disposed of, the enforcers turn their attention to the downstream providers that accepted the payments. 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 Millennium. Since September 2017, more than a dozen physicians have been charged resulting in settlements of over $2 million.

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.

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 principals 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 Wave 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.

Focus On: New Project Aims to Provide Legal Guidance Needed to Do Business in Genomics

Technology changes faster than the laws designed to regulate it. Thus, while DNA testing has changed medicine and fueled growth in the lab industry, it has also created new legal challenges that few labs are prepared to deal with. As the journal Science reports, doctors and other providers are now facing lawsuits raising novel questions and untested theories designed to hold them liable for how they offer genetic testing, interpret tests and counsel patients about the process. And this legal confusion and lack of clarity pose barriers to progress. The good news is that a new project called LawSeq may soon provide the legal guidance industry and other stakeholders need to manage liability risks in carrying out their genomics endeavors.

The LawSeq Project

The three-year, $2 million LawSeq project, which is nearing completion, is sponsored by National Human Genome Research Institute (NHGRI), National Cancer Institute (NCI) and National Institutes of Health (NIH). It's based cooperatively at the University of Minnesota and Vanderbilt University, where a working group of top legal and scientific experts are analyzing current U.S. federal and state legislation and regulation of translational genomics with the objective of producing generate guidance to industry and other stakeholders.

Continued on page 10

Labs IN COURT

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

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:

Self-Disclosed SVT Payment Settlements (January through May 2019)		
Date	**Lab**	**Settlement Amount**
Jan. 24	Northern Kentucky Center for Pain Relief	$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

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.

West Virginia Medicaid Recovers $17 Million for $8.5 Million Opioid Scam

Case: A subsidiary of Acadia Healthcare Co. has agreed to pay $17 million to settle charges of falsely billing West Virginia Medicaid for opioid-related tests. The DOJ claims that over a six-year period, Acadia-owned drug addiction centers across the state billed Medicaid directly for moderately to highly complex blood and urine analyses actually performed in a San Diego reference lab, charging Medicaid substantially higher rates than the centers paid the California lab. By the time it was uncovered, the scheme had cost West Virginia $2.8 million and the federal government $6.3 million.

Significance: The double penalty, i.e., $17 million settlement for an $8.5 million loss, is no accident. First, Acadia is a high-profile, publicly traded company with over $760 million in reported 2019 Q1 revenues. The other aggravating factor is that this case took place in West Virginia, a relatively poor state whose relatively high opioid addiction rate has placed a significant burden on the state's Medicaid program. Acadia subsidiary CRC Health runs outpatient facilities in several towns across West Virginia.

Authors of Genetic Testing Conspiracy Preying on Seniors Sent to Jail

Case: It's off to jail for the ringleaders of a conspiracy to bill Medicare for $430K worth of genetic tests. The leading defendant, a lab sales rep, posed as a representative of The Good Samaritans of America to get access to senior citizens living in low-income housing communities and used fear tactics to persuade them to submit to genetic testing suggesting that they'd get heart attacks, stroke and cancer if they weren't tested. The defendant recruited providers on Craigslist and paid them thousands of dollars per month to sign requisition forms ordering tests for patients they never actually saw. He and his co-conspirators in turn received over $100K in commission payments from the labs which they divided among themselves.

Significance: The sentence was stiff: 50 months in prison, three years of supervised release, $434,963 in restitution and forfeiture of another $66,844. Two weeks later, another of the co-conspirators was sentenced to 19 months and a third to 13 months in prison.

Focus On: New Project Aims to Provide Legal Guidance Needed to Do Business in Genomics, *from page 7*

Among the LawSeq project team's first initiatives:

- Creation of a searchable online database of relevant law and an annotated bibliography for free public access;
- Publication of analyses and recommendations to help shape the law as it pertains to genomic medicine;
- Staging of a national conference (a video will soon be available at the conference website).

Importance of Protocol

Providing such information will help create standards, which will support growth in this burgeoning field. As Science points out, the potential impact for labs is significant.

For example, there is currently no established protocol when understanding of a gene variant evolves after the initial testing. Science notes how a DNA change of unknown significance may later be reclassified to raise the risk of ovarian cancer. What is a lab's responsibility in this situation? Should attempts be made to recontact patients? What if patients can't be reached?

Moreover, there are issues if it becomes commonplace for labs and doctors to recontact patients, because those that don't may face legal risks.

The LawSeq group of scientists and legal experts are addressing these and similar concerns.

FDA Watch: Agency Okays Marketing of Zika Test for First Time, *from page 1*

Aedes species mosquito. Although many people with Zika virus infection experience no symptoms, the virus can pose potentially serious risks to the public health. Links between Zika virus infection and neurological complications (i.e., Guillain-Barré Syndrome), as well as microcephaly (abnormal smallness of the head) and other poor outcomes associated with Zika virus infection during pregnancy, have increased the importance of having diagnostic tests available for Zika virus.

In 2016, the Centers for Disease Control and Prevention (CDC) announced that limited local mosquito-borne Zika virus transmission had been

reported in the continental United States. In 2018 and 2019, no such local transmission was reported.

About the Test + Authorization

The ZIKV Detect 2.0 IgM Capture ELISA is designed to identify proteins (antibodies) produced by the body's immune system when it tests for Zika virus infection in the blood. IgM antibodies indicate an early immune response. The test is for use only in patients with clinical signs and symptoms consistent with Zika virus infection, and/or who meet the CDC's Zika virus epidemiological criteria, such as a history of residence in or travel to a geographic region with active Zika transmission at the time of travel. The FDA authorization doesn't cover testing of blood or plasma donors.

In samples from patients collected seven days or later after the onset of symptoms, the InBios Zika kit correctly identified over 90% of patients confirmed positive for Zika IgM and over 96% of patients confirmed negative.

Results of ZIKV Detect 2.0 IgM Capture ELISA are intended for use in conjunction with clinical observations, patient history, epidemiological information and other laboratory evidence to make patient management decisions. The assay also differentiates Zika IgM from those infected with other flaviviruses (such as dengue or West Nile virus) which cross-react with Zika antibodies

Why Now + Why InBios?

Moving beyond EUA to marketing authorization is a seminal shift in FDA policy. FDA Acting Commissioner Ned Sharpless, M.D., sheds light on the agency's thinking. "At the onset of the Zika virus outbreak, when little was known about the disease or how to diagnose it, the FDA worked quickly with manufacturers to encourage the development of diagnostic tests and ensure they were available using our emergency use authorities," Sharpless explained.

Comfort with the effectiveness of the InBios Zika assay enabled the agency to take the next step. According to InBios, the assay was evaluated via testing 807 unique specimens—353 from test subjects at sites where Zika is endemic and 256 subjects at non-endemic sites. In samples from patients collected seven days or later after the onset of symptoms, the InBios Zika kit correctly identified over 90% of patients confirmed positive for Zika IgM and over 96% of patients confirmed negative.

The authorization doesn't impact the availability of the 14 other Zika nucleic acid diagnostics available under EUAs.

Zika Tests with EUA Clearance from FDA

Zika Tests with EUA Clearance from FDA	
Test	**Company**
CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay	Zika MAC-ELISA
CDC Trioplex Real-time RT-PCR Assay	Trioplex rRT-PCR

Continued on page 12

FDA Watch: Agency Okays Marketing of Zika Test for First Time, *from page 11*

Zika Tests with EUA Clearance from FDA	
Test	**Company**
Zika Virus RNA Qualitative Real-Time RT-PCR	Focus Diagnostics, Inc. (subsidiary of Quest Diagnostics)
RealStar Zika Virus RT-PCR Kit U.S.	Altona Diagnostics GmbH
Aptima Zika Virus assay	Hologic, Inc.
Viracor-IBT Laboratories, Inc.'s Zika Virus Real-time RT-PCR Test	Viracor-IBT
VERSANT® Zika RNA 1.0 Assay (kPCR) Kit	Siemens Healthcare Diagnostics Inc.
xMAP® MultiFLEX™ Zika RNA Assay	Luminex Corporation
ZIKV Detect™ IgM Capture ELISA	InBios International, Inc.
LightMix® Zika rRT-PCR Test	Roche Molecular Systems, Inc.
Sentosa® SA ZIKV RT-PCR Test	Vela Diagnostics USA, Inc.
Zika Virus Detection by RT-PCR Test	ARUP Laboratories
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