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For Clinical and AP Laboratories and Pathology Practices

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INSIDE THIS ISSUE

Compliance Perspectives: How the New OIG Fraud Risk Indicator System Heightens the Imperative of Self-Disclosure

As hard as you try to keep your lab 100% compliant with healthcare fraud and abuse laws, you may discover that an inadvertent violation has occurred. At that point, the compliance imperative switches from prevention to damage control. Your basic choice: cover-up or self-disclose. Leaving aside the morals and the fact that the feds, state enforcers and whistleblowers are making monumental strides in spotting false claims violations, cover-up exposes your lab to significantly heightened liability risks, including the risk of total exclusion from government health programs. While these things are intuitively obvious, the new OIG Fraud Risk Indicator (FRI) system is a very practical and concrete illustration of the risks of cover-up and imperative to self-disclose.

The FRI System

The OIG launched the FRI in September 2018 as a tool to assess "the future risk posed by persons who have allegedly engaged in civil healthcare fraud" for purposes of exercising its authority to

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Case of the Month: Another MD-Owned Lab Gets Busted for Urine Drug Test Abuses

Fraudulent utilization and billing of urine drug screening first became a priority for federal enforcers since the $256 million Millennium settlement of 2016. But the opioid crackdown has heightened the urgency. At the center of the bull's eye are Medicare and Medicaid billing abuses committed by physician-owned drug abuse, rehab and pain clinics. The most recent $4.1 million settlement by the physician owner of a now shuttered Milwaukee mental health clinic is in many ways typical of what's been happening for the past three years.

The Acacia Case

Dr. Abraham Freund acquired the Acacia Mental Health Clinic LLC in 2009 recognizing its enormous potential as a

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exclude alleged fraudsters from federal healthcare programs. The FRI comes into play when the agency is negotiating a settlement agreement with a lab or other provider that has allegedly committed a False Claims Act (FCA) violation to decide how draconian the punishment should be, specifically:

- Is exclusion necessary to protect federal healthcare programs and beneficiaries?
- If exclusion is not necessary, what, if any, future controls are necessary to ensure the settling party's future compliance and prevent the risk of future violations, e.g., requiring the person to enter into a Corporate Integrity Agreement (CIA) with the OIG?

The OIG uses the FRI to answer these questions by assigning the settling party to one of five risk categories, each of which calls for different case outcomes:

OIG FRI Risk Categories

Risk Category	Description	Case Outcome
High Risk/ Exclusion	**Individuals & entities posing the highest future risk of fraud**	**Exclusion from federal healthcare programs & listing in OIG Exclusions Database**
High Risk/ Heightened Scrutiny	**Individuals & entities posing significant future risk of fraud who refuse to enter into a CIA***	**No exclusion but unilateral monitoring by or other "robust integrity obligations" to OIG (and/or state Medicaid fraud agency)**
Medium Risk/CIAs	**Individuals and entities who agree to enter into a CIA**	**Compliance with terms of the CIA**
Lower Risk/ No Further Action	**Individuals and entities who pose a relatively low risk of future fraud**	**Case closed with no CIA or additional measures to ensure future compliance**
Low Risk/ Self-Disclosure	**Individuals and entities that disclose evidence of potential fraud to OIG and demonstrate that they have an effective compliance program**	**Case closed more quickly with lower penalties and no CIA or additional measures to ensure future compliance**

Note:

* Under OIG published criteria, high risk violators can avoid exclusion without a CIA under two limited circumstances:

1. They self-disclose the fraudulent conduct, cooperatively and in good faith, to OIG; or

LCA

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2. They agree to robust integrity obligations with a State or the DOJ and OIG determines these obligations are sufficient to protect the Federal health care programs.

The OIG's 4 Classification Criteria

How does the OIG decide which risk category to assign to a particular FCA offender in an actual settlement? In April 2016, before the FRI took effect, the OIG published the four criteria it proposed to use:

1. Nature & circumstances of the conduct, including whether the conduct:

- Caused or had the potential to cause physical, mental, financial or other harms to beneficiaries or other patients;
- Caused or had the potential to cause financial loss to federal healthcare programs;
- Was part of an ongoing pattern of misconduct;
- Occurred over a long period of time; and
- Is a repeat or continuing violation, including a breach of a current CIA.

2. Conduct during the investigation, with the following constituting indications of higher risk:

- Obstruction or attempts to obstruct the investigation, audit or internal or external reporting of the unlawful conduct;
- Attempts to conceal the unlawful conduct;
- Failure to comply with a subpoena within a reasonable time;
- Occurred over a long period of time; and
- Is a repeat or continuing violation, including a breach of a current CIA.

By contrast, the following are indications of lower risk include:

- Doing an internal investigation;
- Self-disclosing the conduct cooperatively, in good faith and before becoming aware of the government's investigation, if any;
- Acceptance of responsibility for the conduct; and
- Cooperation or promises to cooperate with the investigation.

3. "Significant ameliorative efforts" call for a lower risk score. Examples:

- Imposing appropriate discipline on individuals responsible for the unlawful conduct;
- Significantly increasing the resources the provider organization invests in the compliance function;
- Post-violation acquisition of the organization by an entity with a good compliance record and program; and

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- Post-violation training or education received by licensed individuals.

4. Compliance history, including previous self-disclosures to OIG, CMS (of Stark Law violations) and/or CMS contractors (of non-fraud overpayments). While having a compliance program that incorporates the U.S. Sentencing Commission Guidelines Manual's seven elements of an effective compliance program doesn't help you get a lower risk score, not having such a plan is a factor calling for a higher risk score.

Impact on Your Lab: The 4 Benefits of Self-Disclosure

In deciding how to respond to any FCA violations you discover, keep in mind the four things that self-disclosure of violations to the OIG does to reduce your risks of exclusions and penalties under the FRI system:

- Self-disclosure will get you the lowest possible risk score, Low Risk/Self-Disclosure, provided that you:
  - Make the disclosure in good faith;
  - Disclose before learning that the government is investigating your lab; and
  - Are able to show the OIG that you have an effective compliance program.
- Even if you don't qualify for Low Risk/Self-Disclosure, the fact that you self-disclosed the violation will be an important factor indicator of lower risk that the OIG will weigh in deciding which of the risk categories to assign your lab;
- Even if you're in the high-risk realm, self-disclosure may enable you to avoid exclusion and perhaps even the need to enter into a CIA with the OIG via the High Risk/Heightened Scrutiny categorization; and
- If, heaven forbid, your lab gets into this situation again, self-disclosure will count as a risk mitigating factor in any future FCA settlements you negotiate with the OIG.

8 Other Steps to Take to Reduce Your FRI Risk Score

Although self-disclosure is the most potent, it's by no means the only thing you can do to help your lab secure the lowest possible risk score under the OIG's FRI system. Other FRI risk mitigation measures include:

1. Launching an internal investigation immediately after discovering the FCA violation;
2. Accepting responsibility for the violation;
3. Cooperating or agreeing to cooperate with the subsequent OIG investigation;
4. Appropriately disciplining any lab staffers you determine are responsible for the violation;
5. Making a significant increase to your lab compliance program, e.g., by creating a new, independent compliance officer position;

6. Being acquired by a company with a good compliance record and effective compliance program; and
7. Ensuring that individuals receive enhanced education or training to prevent a recurrence; and
8. Implementing any other necessary remedial measures to fix the problems that caused the violation and ensure it doesn't happen again.

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source of Medicaid drug testing revenues. He soon implemented new rules requiring every patient to provide a urine sample for every type of visit, even when they weren't being seen for drug abuse issues, according to the government's lawsuit. Every sample collected was tested for the same drugs.

From Paper to Gold-Plated Technology

At first, Acacia used a simple "pee in a cup" test detecting the presence of several drugs which was reimbursable at $20 but often upcoded to nearly 10 times that amount. But in November 2012, Acacia bought a $40,000 analyzer which raised the level of reimbursement to $300 per test. Subsequent technological upgrades allowed Acacia to perform and bill for more complex and expensive tests to the point where the clinic was getting paid an average of $474.66 by 2013. Medicaid reimbursement grew from $332K in 2011 to $3.3 million (for nearly 9,000 urine drug screens) in 2014. Between 2011 and 2015, Acacia was accounting for an astounding 99% of all Wisconsin Medicaid payments for mental health and substance abuse counseling services.

The Whistle Blows

As is often the case, Acacia was undone by an inside source. In 2013, nurse practitioner Rose Presser filed a whistleblower suit accusing the clinic of requiring excessive drug screens and prescription refills as well as billing initial appointments as "assessments." After initially declining to intervene, the DOJ had a change of heart.

Last month, Freund agreed to settle the case for $4.1 million (of which the whistleblower will be entitled up to 30%) and a 20-year Medicare and Medicaid exclusion. The one part of the settlement that makes it different from previous cases is the inclusion of charges that Acacia, Freund and his son, Isaac, falsely billed Medicaid for telemedicine services provided by psychiatrists located outside the US.

Analysis: Why Physician-Owned Labs Have Become the Primary Target

Urine drug test abuse has attracted the attention of whistleblowers and prosecutors because it amalgamates two forms of high-priority misconduct:

- Traditional Medicare fraud, i.e., generation of enormous revenues in

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overcharges or services that aren't medically necessary; and

- Promotion of both legal and illegal opioid use.

Although big testing labs like Millennium have been involved, much of the recent focus has been on rogue physicians, particularly those who perform tests out of their own offices and labs. What makes these testing scams cases even more egregious is that the victims, which typically include the indigent, the mentally ill and patients with current or previous drug addictions, are often forced to undergo testing so that doctors can turn a profit.

Compliance Alert: Inova Genomics Warning Letter May Signal Step-Up in FDA LDT Enforcement

By Danielle Sloane and Elaine Naughton, Bass, Berry & Sims PLC

Although it's a continual topic of discussion, FDA enforcement in the realm of laboratory developed tests (LDTs) has been relatively quiet in recent years. But that might have all changed on April 4, 2019 when the FDA issued a warning letter to Inova Genomics Laboratory (Inova) for "illegally marketing certain genetic tests that have not been reviewed by the FDA for safety and effectiveness."

The FDA Warning Letter

The warning letter is aimed at Inova's MediMap tests, which are genetic tests marketed for predicting medication response, reducing negative side effects from certain medications, discovering the right drug and the right dose for a patient and avoiding trial-and-error prescribing by testing patient receptivity to drugs. Specifically, the warning letter highlights a pair of tests:

- MediMap Plus, which is designed to provide insights into how a patient might respond to a variety of drugs including those used for anesthesia, cancers, infections, attention-deficit/hyperactivity disorder, depression, anxiety, and diabetes; and
- MediMap Baby, which analyzes a newborn's genes that influence response to 24 medications.

According to the FDA, Inova's website claimed that the tests provide "actionable and informational guidance" and that "[h]ealthcare providers can use these results confidently in making treatment decisions." Many of the drugs for which the tests produce results include antidepressants or opioids, which can pose serious health risks if the improper dose is given or if the patient stops taking the medication altogether.

The FDA Press Release

In its press release announcing the warning letter, the FDA commented that it "is unaware of any data establishing that Inova's test can help patients or health care providers make appropriate treatment decisions for the listed drug." The FDA stated that this warning letter "reflects the agency's commitment to monitor the pharmacogenetics test landscape and take action when appropriate to address a significant public health risk."

The Director of the FDA's Center for Devices and Radiological Health explained that the FDA is "particularly concerned about pharmacogenetic tests that claim to predict patients' responses to specific medications where such claims have not been established and are not described in the drug labeling and continue to warn patients and health care professionals that they should not rely on these tests for treatment decisions."

What It Means

The warning letter highlights that, according to Inova's website, the "MediMap tests may be ordered by a lab physician in which case test results are provided directly to patients," which "could lead to patients inappropriately increasing, decreasing, or stopping their medication without their physician's involvement. . . ."

We have explored the FDA's skepticism of laboratory relationships and affiliations with the ordering practitioner before. (See "Marketing Laboratory Tests to Consumers: Is a Practitioner Order Enough to Avoid FDA Enforcement?" *Lab Compliance Advisor (LCA)*, March 21, 2016.) And what we've seen is that it's not only a physician order, but the independence of the physician behind the order, that may make the difference between LDT enforcement discretion and direct-to-consumer (DTC) enforcement action.

The letter gave Inova 15 days to respond to the FDA with the steps it has taken to correct the noted violations. In an email, Inova stated that it has promptly responded, it takes the FDA's concerns seriously and it's assessing the appropriate path forward to address them.

TAKEAWAY

This warning letter should serve as a reminder to the lab industry on two important points:

1. The FDA can and will take action against LDTs, particularly ones being marketed directly to consumers; and
2. If the physician who orders the test is affiliated with the lab, the physician order may not be sufficient to extricate an LDT from being considered DTC in the eyes of the FDA.

About the Authors

Danielle Sloane, of Bass, Berry & Sims, helps national life science and healthcare clients navigate the complex maze of federal and state healthcare laws and regulations. With an analytical eye, Danielle helps her

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clients mitigate legal risk and achieve regulatory compliance consistent with their business goals. Danielle's practice involves fraud and abuse, compliance, regulatory and operational matters, transaction structuring and diligence and government investigations. Danielle advises clients on how they can best innovate, evolve and improve patient care within the confines of current healthcare regulatory laws. Danielle was recognized by Law360 as a Rising Star in healthcare in 2017.

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Labs IN COURT

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

WV Hospital & Marketing Consultant Sued for Elaborate Kickback Scheme

Case: A new DOJ lawsuit accuses a West Virginia non-profit hospital and its business consultant of seeking to dominate the Ohio Valley market by bribing physicians for referrals. The scheme began in 2005, according to the complaint, when Wheeling Hospital hired R&V Associates to turn around its sagging financial fortunes. The plan: Enter into contracts providing beyond market value compensation to the region's leading OB/GYN, radiology oncologists, cardiologists and pain management physicians for referring patients to the Hospital. As a result of these deliberate Antikickback Statute and Stark Law violations, the Hospital went from $50 million in losses to massive profits.

Significance: The complaint, which arose from a 2017 whistleblower lawsuit, details the contractual arrangements with the physicians who eagerly accepted the millions of dollars' worth of overpayments even though they knew it was illegal, and how R&V and the Hospital carefully tracked individual physician referral records and adjusted their compensation accordingly. Meanwhile, the Hospital has filed a breach of fiduciary lawsuit against its former executive VP, who's charged with carrying out the scheme with R&V.

Urgent Care Centers Settle E/M Upcoding Charges for $2 Million

Case: The owners/operators of CareWell urgent care centers in Massachusetts and Rhode Island have agreed to shell out $2 million for improper coding of Evaluation and Management services. CPT code selection for E/M services is based on the number of body systems a provider must evaluate to diagnose a patient and who does the examination, e.g., nurse practitioner or physician. CareWell is accused of falsely inflating the level of E/M services performed and failing to properly identify who provided them. The whistleblower who brought the initial claim will get 17% of the recovery.

Significance: The part of this case that's relevant to labs are the alleged methods CareWell used to carry out the upcoding scheme, which are analagous to things labs

have been charged of doing to inflate coding for testing services, including:

- Requiring medical staff to examine and document at least 13 body systems during medical inquiries and 9 systems during physical exams regardless of patients' actual complaints;
- Uploading encounter plan templates onto electronic medical records software asking "yes/no" questions about particular body systems that medical personnel had to ask each patient regardless of whether those questions were medically necessary; and
- Programming the template to list "no" as the default answer to any question that wasn't asked to make it look like the particular body system to which the question related was examined.

Kentucky Lab Pays $125K to Settle Self-Disclosed SVT False Billing Charges

Case: VerraLab JA, LLC, has agreed to pay $125,983 after self-disclosing that it billed Medicare for specimen validity tests (SVT) performed to authenticate urine samples for drug testing. Unlike the underlying urine drug test which is actually used to manage treatment, SVT is not considered medically necessary by Medicare where its sole purpose is to validate the specimen, i.e., verify that it hasn't been adulterated.

Significance: In February of 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. VerraLab is the fourth settlement involving SVT payments that OIG has reported in the first quarter of 2019. The other three also involve providers from the Ohio Valley area:

Self-Disclosed SVT Payment Settlements (Jan. thru March 2019)

OIG FRI Risk Categories		
Date	**Lab**	**Settlement Amount**
Jan. 24	**Northern Kentucky Center for Pain Relief**	**$126,779**
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 (MSK) (Louisville, KY)**	**$69,776**

Federal Jury Finds Trio Guilty of $3.5 Million Lab Kickback Conspiracy

Case: Three men from the Chicago area were convicted of taking bribes for sending blood, urine and saliva samples to St. Louis lab AMS Medical Laboratory, Inc. for testing subsequently billed to Medicare and Medicaid. Under the elaborate scheme which generated $3.5 million in false test billings, the defendants sent AMS samples

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collected at health fairs held at churches and businesses in Illinois and Indiana under the names of doctors who didn't order the tests or even know the patients; in exchange, they received a cut of 50% of the profits—up to $200 per sample—from AMS' managing partner.

Significance: The Chicago three are among 10 defendants in the case, including the managing partner who pled guilty last year and a physician convicted by a jury last October for pocketing kickbacks in connection with the scheme. They'll be sentenced in July.

Co-Owner of Kentucky Lab Pleads Guilty to Reference Lab Conspiracy

Case: This story is about a medical billing firm T. Monroe Medical Billing and its toxicology lab client Compliance Advantage LLC (CAL) that were partially owned by the same gentleman. The problems began in 2016 when Medicaid, Aetna and Humana accused the lab of improper billings and cut payments to the facility. Aetna also demanded that CAL repay $750K. To get around the ban and generate revenue, the co-owners cut a reference lab agreement with a third lab (not named in the court papers) enabling Monroe and CAL to bill the payors for tests that were actually performed by CAL in the name of the third lab. The cut: 60/40 with the third lab taking the 40%. The reference lab agreement was backdated to further the deception.

Significance: One of the co-owners pled guilty to one count of conspiracy and now faces up to five years' in prison when he's sentenced in June. The other co-owner who had a partial ownership interest in both CAL and Monroe will answer to a higher authority, having died in 2017.

Healthcare 'Trial of the Century' Ends in Guilty Verdict against Esformes

Case: After a seven-week trial, a federal court convicted Florida healthcare executive Philip Esformes of 20 charges in carrying out a $1.3 billion Medicare fraud scheme, the biggest in history. In addition to paying doctors to refer patients to his elaborate nursing homes, labs and home health agency network from 2009 to 2016, Esformes paid a regulatory official thousands of dollars to sound the warning when government inspectors were planning to inspect the facilities.

Significance: Although not strictly about labs, the Esformes case has been called the healthcare trial of the century due to the sheer size of the scheme. And it's not over. Esformes' attorneys say they plan to appeal the verdict.

FDA Extends Deadline to Comment on Proposed 510(k) Pathway Reform

April 22, 2019 was supposed to the last day to comment on newly proposed FDA guidance on changing the Section 510(k) premarket review process for new devices and diagnostic tests. But just before that date, the agency extended the comment deadline 30 days to May 22. Here's a quick

review of the proposal.

The Proposed New Pathway

Under current FDA rules, device and diagnostic test manufacturers can use the 510(k) pathway to secure expedited approval for new products that they can show are substantially equivalent to products that were grandfathered in when Congress created the pathway back in 1976. So, it goes without saying that the pathway is antiquated and in desperate need of an overhaul. Last February, the FDA floated a proposal to create a new "Safety and Performance Based Pathway" that would base new product approvals on consensus standards rather than direct predicate comparisons with previously approved devices.

The FDA's 5 Questions

In its notice requesting comments on the new proposal, the FDA posed a series of six questions:

1. Should the FDA publicize a list of devices or manufacturers currently on the market that rely on predicate technology for more than a specific number of years in an attempt to use embarrassment as motivation for modernization?
2. If so, what number of years should that be?
3. Should the FDA consider using other criteria to inform our point of reference?
4. Are there other actions FDA should take to promote the use of more modern predicates?
5. Should the FDA consider certain actions that might require new authority, such as making at least some older devices ineligible as predicates?

(For more on the FDA proposal and its impact on labs, see *National Intelligence Report (NIR)* March 11, 2019.)

OIG Monthly Work Plan Review: April 2019

Among the 10 new Work Plan items this month, three may have potential ramifications for at least some labs.

1. Medicaid Managed Care Organization Denials

Issue: The State Medicaid agency and the federal government are responsible for financial risk for the costs of Medicaid services. Managed care organizations (MCOs) contract with state Medicaid agencies to ensure that beneficiaries receive covered Medicaid services. The contractual arrangement shifts financial risk for the costs of Medicaid services from the state Medicaid agency and the federal government to the MCO, which can create an incentive to deny beneficiaries' access to covered services.

OIG Action: OIG review will determine whether Medicaid MCOs

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OIG Monthly Work Plan Review, *From Page 11*

complied with federal requirements when denying access to requested medical and dental services and drug prescriptions that required prior authorization.

2. Review of Monthly ESRD-Related Visits Billed by Physicians or Other Qualified Healthcare Providers

Issue: Most physicians and other practitioners (e.g., clinical nurse specialists, nurse practitioners, or physician's assistants) who manage the care of patients who receive outpatient dialysis services at end-stage renal disease (ESRD) facilities are paid a monthly capitation payment (MCP) for ESRD-related physician services. The MCP amount is based on the number of visits provided within each month and the age of the ESRD beneficiary. The physician or other practitioner can bill only one of three current procedural terminology (CPT) codes for ESRD-related visits of one per month, two to three per month, or four or more per month (CMS, Medicare Claims Processing Manual, Pub. No. 100-04, chapter 8, § 140.1).

OIG Action: The Comprehensive Error Rate Testing program's special study of the Healthcare Common Procedure Coding System codes for ESRD-related services found that for some codes, approximately one-third of the payments for ESRD-related services were improper payments due to insufficient documentation, incorrect coding, or no documentation submitted (CMS, Medicare Quarterly Provider Compliance Newsletter Guidance to Address Billing Errors, volume 5, issue 3, April 2015). OIG will review whether physicians or other qualified healthcare professionals billed monthly ESRD-related visits in accordance with federal requirements (Social Security Act, §§ 1815(a) and 1833(e)).

3. Audit of National Institutes of Health Information

To see the full article, including the third item, go to: https://www.g2intelligence.com/oig-monthly-work-plan-review-april-2019/