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INSIDE THIS ISSUE

Compliance Perspectives: 5 Ways to Avoid Kickback Risks When Placing Phlebotomists in Ordering Physician's Offices

It's not uncommon for labs to place a phlebotomist in a physician's office to collect and process samples for testing. While not strictly illegal, this practice raises bright red flags under kickback laws. So, it's imperative to carefully vet your in-office phlebotomist arrangements to ensure they don't cross any kickback lines. Here's how:

The Legal Risks of In-Office Phlebotomist Arrangements

The Anti-kickback statute (AKS) bans labs from offering or providing physicians anything of value to induce or reward the referral of patients covered by Medicare, Medicaid and other federal health care programs. The Stark Law and state antikick laws impose similar restrictions. The problem is that while you might not think of it as such, placing a phlebotomist

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Marketing Pitfalls to Avoid: Deceptive Advertising—the Other Kind of "False Claims"

We all know that marketing activity is a breeding ground for potential lab liability. But while most labs are sensitive to the risks posed by the Antikickback Statute, Stark Law and False Claims Act, federal false advertising laws may fly under the radar. Here's a quick overview of one of the key false advertising laws and a recent case illustrating how its principles play out in real life lab company disputes.

The Lanham Act

In some ways, the federal Lanham Act is to lab test advertising what the False Claims Act is to lab test billing. It bans labs from making a false statement in a commercial advertisement about their own or another lab's product. To be found guilty under the Act, at least three things must be proven:

- The statement made in the advertisement is false;
- The statement actually deceived or had the tendency to deceive a substantial segment of its audience; and

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inside the office of an ordering physician may constitute the kind of remuneration that triggers liability.

When Arrangements Are Allowed

The good news is that the OIG has issued a Special Fraud Alert (Alert) specifically allowing these arrangements under certain conditions. As long as it's okay under state law, the OIG says, a lab may make a phlebotomist who collects specimens from patients for testing at the lab "available to a physician's office." Mere placement of a phlebotomist wouldn't necessarily constitute an inducement banned by the AKS (or, by implication, the Stark Law); but, the OIG continues, the arrangement becomes problematic "when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff."

Implement 5 Safeguards to Minimize Kickback Risks

Even though the OIG issued the Alert way back in 1994, it remains the definitive word on the legality of in-office phlebotomist arrangements between testing labs and ordering physicians. Bottom Line: The key to protecting your lab from liability risks is to structure your arrangement so that it meets the OIG's parameters. Specifically, there are five things you should do:

1. Make Sure Arrangement Isn't Banned by State Law

As the Alert acknowledges, in-office placement of lab phlebotomists is only legal if it's allowed under state law. And at least five states (CA, FL, NJ, NY and PA) specifically ban or severely restrict such arrangements. (For a detailed analysis of the state laws and how to comply with them, see Lab Compliance Advisor, (LCA), **Deborah Kantar Gardner**, Esq., "Laboratory Phlebotomists in Physician Offices? States Increasingly Saying 'No'")

2. Limit Phlebotomist Duties to Strictly Lab-Related Tasks

The key to the arrangement's legality is the scope of the phlebotomist's duties, which should be strictly limited to tasks directly related to the collection and processing of the specimen to be tested. "Where the phlebotomist performs clerical or medical functions not directly related to the collection or processing of laboratory specimens, a strong inference arises that he or she is providing a benefit in return for the physician's referrals to the laboratory," the Alert warns.

3. Specify Which Tasks Phlebotomist May & May Not Perform

Although not expressly required by the Alert, Savannah, Georgia, laboratory compliance attorney **Adam Walters** strongly advises spelling out the exact tasks that phlebotomists can and cannot perform. The chart below comes from the language Walters has prepared for his own clients

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Permissible Duties of In-Office Phlebotomist	
OK	**Not OK**
▶ Collecting specimens for testing at lab, affiliated reference lab or lab with collection agreement ▶ Specimen preparation for transporting ▶ Specimen packaging for transporting ▶ Clerical duties directly related to handling + processing of lab specimens, e.g.: • Obtaining billing information for lab's use • Ensuring accurate completion of lab requisition form • Confirming processing of specimen reports	▶ *Assisting, in any manner with Point of Care testing with a CLIA waived cup or physician's lab office analyzer in which physician is billing ▶ *Performing medical or nursing assistant duties for physician's patients, including but not limited to taking of vital signs ▶ *Any other medical tasks that are customarily the responsibility of the physician's office staff ▶ *Any administrative and/or clerical duties that are customarily the responsibility of the physician's office, including but not limited to: • Answering the physician facility's phones • Filing and/or reviewing patient files • Registering patient demographics into physician facility's computer system ▶ *Providing or offering any gifts or personal services for physician's facility providers, management or office staff

(which is incorporated as a Model Agreement on page 5.).

4. Ensure Strict Monitoring of Phlebotomist

The mere existence of a contract between the lab and physician that bans the phlebotomist from performing services unrelated to specimen collection isn't enough to satisfy the OIG's kickback concerns, according to the Alert. The contractual restriction must be "rigorously enforced" and the phlebotomist "closely monitored" by his/her employer.

5. Ensure Physician Doesn't Charge for Phlebotomist's Services

Last but not least, the host physician may not charge payors for the services the phlebotomist provides.

Takeaway

Although the Alert and above analysis specifically addresses phlebotomists, you can easily adapt it for any other personnel you place in ordering physicians' office to assist with collecting and processing specimens for testing at your lab.

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MARKETING PITFALLS TO AVOID, *from page 1*

- The deception is material, i.e., likely to influence the purchase decision.

The Quidel v. Siemens Case

These rules have been the focal point of a long-running legal battle between two major labs that offer competing blood tests to detect Graves' disease by measuring thyroid stimulating immunoglobins. Such tests come in two basic varieties:

- TSH receptor antibody (TRAb) assays that detect both stimulating and blocking thyroid immunoglobins (TSI and TBI); and
- TSI tests that detect only stimulating immunoglobins.

Siemens produces Thyretain TSI Reporter BioAssay (Thyretain), a test cleared by the FDA in 2009 as "TSI only." In 2012, Quidel began offering a competing test called IMMULITE. Unlike Thyretain, which is a bioassay, IMMULITE is an immunoassay capable of depicting the concentration of TSI in a sample, rather than just a binary "qualitative" result.

What Happened

The trouble began when Siemens ran advertisements referring to IMMULITE as a "TSI only" product. Quidel took immediate umbrage, insisting that IMMULITE detects both TSI and TBI. Although Siemens eventually dropped the claim, Quidel sued it for false advertising under the Lanham Act. Both sides asked the southern California federal district court to rule in its favor without a trial. After three years of litigation, the court made a ruling dismissing some but not all of the claims without a trial. In so doing, it relied on the three key Lanham Act criteria.

1. Did Siemens Make False Claims about IMMULITE?

The first thing Quidel had to prove to show false advertising is that what Siemens said in its ads about IMMULITE being a "TSI only" assay was false. Naturally, both sides introduced expert opinions supporting their position on the issue. After weighing all the evidence, the court found the evidence inconclusive. That finding would have spelled doom for Quidel had this been an actual trial. But at this point in the proceedings (known as "summary judgment"), the court's job was not to decide if Quidel's Lanham Act was right but whether it deserved to go to trial in the first place. And because the evidence was split, a trial would be necessary to sort out the facts.

2. Did Siemens' Claim Deceive the Market?

Quidel also had to show that people were actually deceived by what Siemens said about IMMULITE in its advertising. But while this issue would be crucial to the ultimate decision, it wasn't a factor for summary judgment since if Quidel could prove the claims were false, the court would automatically infer that at least some part of the market was deceived.

3. Was the Deception Material?

At this point, Siemens still had a chance to win summary judgment and get the court to dismiss the claim without a trial by showing that even if the claims of IMMULITE being a "TSI only" test were false and people were deceived, the falsity wasn't "material" since it didn't affect customers' decision to choose Thyretain over IMMULITE. In determining materiality, the court looked at two segments of the market:

(a) Labs

As even Siemens acknowledged, two major labs, LabCorp and Sonic/CPL, did switch from IMMULITE to Thyretain. But Siemens insisted that its ads had no influence on that decision. The court agreed citing the testimony of officials of both LabCorp and CPL that the decision to use Thyretain rather than IMMULITE was the product of months of rigorous internal study and deliberation (including a validation study by CPL) about which product performed better and had nothing at all to do with Siemens' ads or press releases. The LabCorp official went so far as to decry the lawsuit as "frivolous" because it assumes that the company doesn't "do a very, very rigorous job of vetting our assays and that we can be swayed by marketing."

(b) Physicians

Quidel wasn't finished and insisted that the market included not just labs but also ordering physicians. The court neither agreed nor disagreed; instead, it found that the issue of whether physicians should be included in the relevant market for the assays was a question of fact that the jury would have to decide.

Bottom Line

Each side ultimately got part but not all of what it wanted. Siemens won dismissal of all claims related to false advertising to labs; Quidel secured the chance to go to trial and prove its claims for false advertising to physicians.

Quidel Corp. v. Siemens Med. Sols. USA, Inc., 2019 U.S. Dist. LEXIS 181831

Compliance Tool: Model In-Office Phlebotomist Agreement

The following Model Agreement between a testing lab and a referring physician was created by Savannah, GA, lab compliance attorney **Adam Walters** and structured to minimize kickback liability risks to each party in accordance with the OIG 1994 Special Fraud Alert, which remains the definitive source of federal guidance on the subject. Speak to your attorney about adapting the model for your own use.

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COMPLIANCE TOOL, *from page 5*

IN-OFFICE PHLEBOTOMIST COMPLIANCE AGREEMENT

This In-Office Phlebotomist Compliance Agreement ("Agreement") is made and entered into and shall be effective as of _____ 20__, by and between [INSERT BLANK] (the "Laboratory"), _____ _____ (the "Phlebotomist") and _____ (the "Facility").

WHEREAS, Laboratory hired the Phlebotomist to collect specimens from patients for testing by Laboratory at one or more medical practices (the "Facility");

WHEREAS, the Parties acknowledge and agree that federal and state law, as well as Laboratory's own compliance program, prohibit an in-office phlebotomist from performing services or providing renumeration for the benefit of a referring providers office; and

WHEREAS, Phlebotomist and Facility represent that they will comply with Laboratory's compliance guidelines regarding allowable tasks to be performed by the Phlebotomist.

NOW THEREFORE, in consideration of the mutual covenants set forth herein, the parties hereby agree as follows:

1. Allowable Services. Phlebotomist and Facility acknowledge and agree that the Phlebotomist may perform the following services:
    A. Those tasks directly related to the collection or processing of Laboratory specimens. The following are examples of those tasks:
        i. Collection of specimens from patients for testing at Laboratory, a reference laboratory affiliated with the Laboratory, or a laboratory which has a collection agreement with Laboratory;
        ii. Specimen preparation for transporting; and,
        iii. Specimen packaging for transporting.
    B. Those clerical duties directly related to the handling and processing of Laboratory specimens. The following are examples of those clerical duties:
        i. Obtaining billing information for Laboratory's use; and,
        ii. Clerical duties directly related to the specimen being collected, including but not limited to ensuring accurate completion of Laboratory requisition forms, confirming the processing of Laboratories specimen reports, and facilitating inquiries about specimen reports.
2. Prohibited Services. Phlebotomist and Facility acknowledge and agree that the Phlebotomist may not perform any of the following services:
    A. Any tasks that are customarily the responsibility of the Facility's office staff. The following are examples of such tasks:

i. Assisting, in any manner, with Point of Care testing with a CLIA waived cup or Facility's laboratory office analyzer in which Facility is billing; and,

ii. Performing medical or nursing assistant duties for Facility patients, including but not limited to the taking of vital signs.

B. The performance of any administrative and/or clerical duties that are customarily the responsibility of the Facility's office staff. The following are examples of such administrative and/or clerical duties:

i. Answering Facility telephones;

ii. Filing and/or reviewing patient files; and,

iii. Registration of patient demographics unto Facility's computer system.

C. The provision of any gifts or personal services for Facility's providers, management, or office staff.

3. No Influence. The Phlebotomist and Facility acknowledge and agree that the ordering of laboratory test(s) may only be ordered by a provider, e.g. physician or mid-level practitioner, treating the beneficiary for the purpose of using the results in the management of the beneficiary's medical problems. Accordingly, the Phlebotomist agrees that he/she will not take part in any activities that could influence the ordering provider's decision making, including but not limited to reviewing provider orders, reviewing patient drug regiments, and providing infection control services.

4. Monitoring. Facility acknowledges that Laboratory shall have the right to review the Phlebotomist's performance of this Agreement to verify his/her compliance with the provisions herein, including but not limited to Sections 1, 2, and 3 above, and Facility further agrees to cooperate and provide Laboratory access to the information, records, documents and other materials Laboratory needs to exercise said monitoring functions in a reasonable manner that does not cause Facility to incur any undue costs or business interruptions.

5. Term. This Agreement shall remain in effect as long as Phlebotomist is employed by Laboratory.

6. Remedies. In the event that Phlebotomist and/or Facility violate this Agreement, Laboratory reserves the right to terminate the employment of Phlebotomist and the account of the Facility.

7. Other Agreements. The parties acknowledge and agree that there may be other agreements between the parties, including but not limited an employment agreement. The compliance representations in this Agreement shall supplement, not supplant, any other agreements or arrangements between the parties. The parties further agree that these representations shall supplement, not supplant, any statutory or regulatory provisions applicable to the subject arrangement.

COMPLIANCE TOOL, *from page 7*

SIGNATURES

LABORATORY:_____

By:_____

Its:_____

PHLEBOTOMIST:_____

By:_____

FACILITY: _____

By:_____

Its: _____

LCA Source

Adam M. Walters, Esq., laboratory compliance attorney, Walters Law P.C., Savannah, GA

Kickbacks: Millennium Free Test Cup Physicians Crackdown Yields First 7-Figure Settlement

The federal crackdown against the physicians and medical practices that accepted free point-of-care test cups from Millennium Health continues. On Oct. 2, 2019, the OIG dropped a bombshell by announcing that a medical practice in North Florida had entered into a $1.128 million settlement. That's the largest such settlement, by far, since the shift from lab payer to physician payees began more than two years. Of course, it dwarfs the $256 million the author of the largest kickback scheme in history, Millennium Health, settled for back in 2016. Here's the latest tally.

Partially Exempt Industries by NAICS Code

Date	Provider(s)	Settlement Amount	Individual Physicians Also Charged?
Oct. 2, 2019	Physicians Group Services, P.A.	$1,128,615	NO
July 12, 2019	Anesthesia Services P.C. d/b/a University Pain Clinic (Detroit)	$44,900	NO
June 14, 2019	HKD Treatment Options, P.C.	$87,650	NO
Dec. 21, 2018	Tulsa Pain Consultants, Inc.	$98,942	YES
Sept. 6, 2018	Doctor's Inlet Pediatrics and Primary Care, P.A., and Avenues Pediatrics and Internal Medicine (Florida)	$58,370	YES

Partially Exempt Industries by NAICS Code (continued)			
Date	**Provider(s)**	**Settlement Amount**	**Individual Physicians Also Charged?**
May 24, 2018	Recovery Pathways, LLC (Michigan)	$64,555	NO
April 5, 2018	Affordable Medical Care f/k/a Andalusia Medical Center (Alabama)	$40,500	YES
Feb. 28, 2018	The Pain Institute, Inc. d/b/a Space Coast Pain Institute (Florida)	$95,302	YES
Dec. 5, 2017	Addiction Medical Care of Norwalk, Practice Management Associates Norwalk, LLC, Addiction Medical Care of Columbus, and Practice Management Associates, LLC (collectively, "AMC") (Ohio)	$79,880	NO
Sept. 27, 2017	Advanced Pain Management (Arizona)	$186,210	NO
Sept. 18, 2017	Parallax Center, Inc. (New York)	$64,203	NO

OIG Work Plan: Agency to Focus on Collection of Medicare Advantage Ordering Provider Identifiers

OIG needs ordering provider identifiers in the Medicare Advantage (MA) encounter data to be available so it can use the data to identify and prevent potential fraud, waste and abuse. However, although OIG recommends, CMS doesn't currently require MA organizations (MAOs) to submit National Provider Identifiers (NPIs) for ordering providers. In previous studies, OIG found that nearly two-thirds of records for clinical labs, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), imaging, and home health services reviewed did not include the NPI for the ordering provider.

Accordingly, the OIG plans to determine the extent to which MAOs obtain the NPIs of providers who order clinical lab services, DMEPOS, imaging services and home health services for MA enrollees and determine how MAOs that don't obtain these identifiers are conducting routine monitoring, auditing and oversight of these types of services. The OIG will also provide updated information on how many MAOs voluntarily submit NPIs of providers who order clinical lab services, DMEPOS, imaging services and home health services to CMS.

Among the other 15 new Work Plan items for November, three may indirectly affect at least some lab providers and companies.

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OIG WORK PLAN, *from page 9*

1. Additional Programming Code for Opioid Toolkit

Issue: In June 2018, the agency issued Using Data Analysis To Calculate Opioid Levels and Identify Patients at Risk of Misuse or Overdose, a toolkit setting out steps for using prescription claims data to analyze patients' opioid levels and identify certain patients at risk of opioid misuse or overdose.

OIG Action: The OIG will extend the toolkit's reach beyond its current SAS programming code to include coding languages, R and SQL.

2. Medicaid Concurrent Eligibility

Issue: State Medicaid agencies pay managed care organizations (MCOs) capitated per-month, per-beneficiary payments. So, if a beneficiary in one state moves to another state, his/her Medicaid eligibility in the first state should end and the MCO in that state should no longer get payments for that beneficiary.

OIG Action: The OIG will check to see if states are making capitation payments to MCOs for beneficiaries after they've moved out of the state.

3. Medicare Payments for Stelara

Issue: Since 2016, total Medicare Part B physician payments for Stelara, an expensive drug used to treat certain autoimmune diseases that's often self-injected by patients in their home, have increased substantially. Such a large increase in payments for a drug that wouldn't typically be covered under Part B seems fishy and might betoken improper billing.

OIG Action: The OIG will:

- Determine if versions of Stelara that are typically self-injected meet the criteria for Medicare Part B coverage;
- Identify factors that may be causing the substantial growth in payments; and
- Determine whether claims for Stelara show evidence of improper billing by physicians.

Labs IN COURT

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

Lab's 'False Positive' Drug Test Report ≠ Defamation of Employee

Case: An Arkansas nurse got fired and reported to the State Nursing Board after failing a urine drug test. It turned out to be a false positive. After getting cleared by the Board, the nurse sued the testing lab, Quest Diagnostics, for defamation. But the federal court found the claim legally invalid. Quest had a qualified privilege to do the tests and report the results to the nurse's employer. After all, that was its job and the employer had a legitimate need to know the information [Skorcz v. Quest Diagnostics Clinical Labs., Inc., 2019 U.S. Dist. LEXIS 180861].

Significance: Reporting an employee's false positive drug test to an employer isn't an act of defamation as long as the lab doesn't deliberately or recklessly falsify the test results or act maliciously. However, the employee may be able to sue the lab for negligence.

SNF Labs Can Separately Bill Medicaid for Blood Glucose Tests

Case: The State of Ohio sued a skilled nursing facility (SNF) for falsely billing glucose lab tests that were already bundled into its per diem Medicaid SNF patient rate as "ancillary and support costs." The labs that performed the tests, although owned by the SNF, were independent labs and thus entitled to bill for the tests, the SNF contended. The Ohio high court agreed and dismissed the false billing charges.

Significance: The key factor in this ruling was that Ohio Medicaid granted the labs approval to operate as independent labs. And the approval was valid under the State Medicaid statute in effect at the time, which required that a lab be independent from: (1) the offices of the attending or consulting physicians, (2) clinics, (3) ambulatory surgery centers and (4) hospitals. The court noted that SNFs weren't on this list and that the prosecution couldn't point to any other laws banning the approval of SNF labs as independent [State v. Amherst Alliance, LLC, 2019-Ohio-4640, 2019 Ohio App. LEXIS 4680, 2019 WL 5887277].

Kentucky Hospital Shells Out $10+ Million to Settle Whistleblower Suit

Case: Ending a case that began as a *qui tam* whistleblower lawsuit, Jewish Hospital & St. Mary's Healthcare Inc., d/b/a Pharmacy Plus and Pharmacy Plus Specialty, has agreed to pay $10.1 million to settle claims of falsely billing for prescription drugs that weren't medically necessary. In addition to serious documentation issues—orders unsigned by a physician and absence of records showing that medications were actually delivered, the hospital allegedly paid kickbacks to patients in the form of free blood glucose testing supplies and waiver of co-payments and deductibles for insulin.

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LABS IN COURT, *From Page 11*

Significance: As is often the case with *qui tam* suits, the case might have been prevented had hospital officials taken the whistleblower, a pharmacist, who stepped forward to report concerns about improper billing of prescription drugs. But when the issues went unaddressed, the pharmacist resorted to litigation, which the federal government eventually joined. For his efforts, he will get $1.85 million of the settlement award.

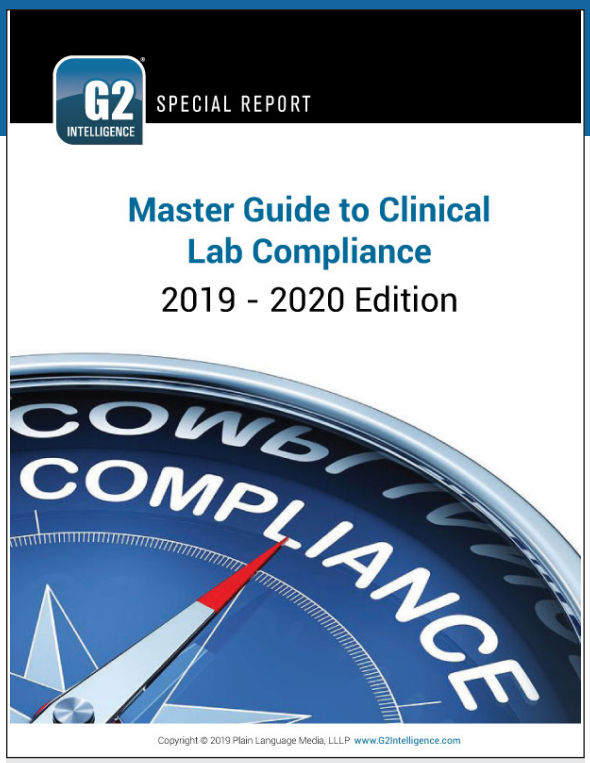
Feds Target Principals of Pacific Northwest Urine Test Billing Scam

Case: A physician-owned testing lab and three individuals were indicted for an alleged kickback scam that generated more than $2 million in falsely billed urine tests. According to federal prosecutors, Molecular Testing Lab (MTL) agreed to pay Northwest Physicians Lab (NWPL) as much as $100K per month for referrals of urine tests billed to Medicare. The payments were disguised as marketing fees even though Washington-based didn't perform any actual marketing services for the Vancouver lab.

Significance: One of MTL's co-founders pled guilty and will pay up to $461,752 in restitution. And in December 2018, MTL agreed to pay $1.777 million to settle allegations for its role in the scam.

Protect Your Lab against Growing Legal Risk!

Master Guide to Clinical Lab Compliance 2019-2020 Edition



Lab Compliance Essentials **covers:**

- Latest Fraud and Abuse Laws
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- Stark Laws
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A Practical, Plain-Language Guide to Protecting Your Lab against Costly False-Claims, Anti-Kickback, and Stark Law Violations

For over two decades, clinical labs have been the target of a relentless stream of **investigations, audits, reviews, lawsuits**—and even **criminal prosecutions**—by the Centers for Medicare and Medicaid Services, and other Federal and State agencies.

Without a doubt, enforcement actions for **False-Claims violations** top the list. But the government has also systematically and aggressively grown the number of investigations into **Anti-Kickback** and **Stark Law violations.**

And that's just the tip of the iceberg. Investigations and **enforcement actions by state governments** have become increasingly aggressive... **whistleblower lawsuits** continue to grow sharply... and the ACA has earmarked **over $350 Million in funds for stepped up enforcement though 2020**, so you can be sure that labs like yours will come under increasing legal scrutiny.

Lab Compliance Essentials gives you the **practical, plain-language help** you need to understand the laws, and take **proven steps to protect your lab** from costly False-Claims, Anti-Kickback, Stark Law, and other legal and compliance violations.

For more information, please visit our website at **G2Intelligence.com/shop**

Or contact Andrea: **888-729-2315**, **Andrea@plainlanguagemedia.com**