G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

NATIONAL INTELLIGENCE REPORT™

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 41st Year of Publication

Vol. 20, Iss. 1, January 2020

INSIDE THIS ISSUE

The Year in Labs Regulation: The 6 Biggest Stories of 2019

"May you live in interesting times."

This ancient Chinese curse extoling the virtues of stability may resonate with those of you who work in the lab industry and have a stake in federal regulation. In fact, 2019 was an interesting year. A lot happened. Unfortunately, much of it was negative and some of it downright scary. And one of the areas where many lab people would have liked something to happen, namely, the development of new LDTs regulations, was frustratingly *un*interesting. Here's a rundown of what G2 Intelligence voted as the biggest lab stories of 2019.

1. Proposed Value Based Care Kickback Relief Leaves Labs in the Cold

CMS finally got serious about meaningful value-based care kickback relief. But while the rules proposed on Oct. 9, 2019 offered goodies

Continued on page 2

Hospital Labs: CMS Pushes Forward with Controversial Price Transparency Rules

Brushing aside the intense objections and negative feedback, CMS pressed forward with price transparency by including as part of the 2020 Outpatient Prospective Payment System final rules the requirement that hospitals disclose to the public their standard charges public, including their negotiated rates with payers. Hospitals lost no time pushing back by filing a lawsuit challenging the rule on First Amendment grounds and asking a federal court to block its enforcement.

The Price Transparency Controversy

The controversy began with an executive order issued by the President to advance the Trump Administration policy of compelling providers to make their prices transparent in advance so that consumers can make financially informed decisions about

Continued on page 10

The Year in Labs Regulation: The 6 Biggest Stories of 2019, *from page 1*

for most everyone in healthcare, the lab industry got a lump of coal in its stocking. The CMS explanation was downright insulting: "On the basis of our historical enforcement and oversight experience, we are concerned that [some labs] . . . might misuse the proposed safe harbors to offer remuneration to practitioners and patients to market their products." In other words, nearly three decades after Operation Labscam, we still don't trust you. The good news is that the proposed rules do offer labs some relief. More importantly, they're a long way from final and labs still have a chance to get CMS to back off and allow it to participate in new exceptions for not just VB care but also EHR and cybersecurity.

2. The Tide Appears to Turn against CMS on PAMA Pricing

After years of frustration, the lab industry finally made significant progress on the PAMA front in 2019. Before the year began, CMS announced that it was adopting an American Clinical Laboratory Association (ACLA) recommendation to treat hospital outreach labs that use the Form CMS1450 14x TOB to bill for non-patient lab services as "applicable laboratories" that had to report commercial payor pricing information.

But while the hope and expectation is that inclusion of these previously excluded hospital labs will positively impact future Medicare reimbursement rates for all labs, much remains to be done to ensure fair prices and rescue what small and freestanding labs remain from the PAMA wrecking ball. To keep up the pressure, the ACLA dusted itself off from a 2018 federal court ruling dismissing its challenge to the legal validity of the CMS pricing scheme and filed an appeal. And in July, the D.C. Circuit Court of Appeal reversed the lower court and said the ACLA could go forward with its case after all. While it may not result in ultimate court victory—at least in the near term—keeping the lawsuit in play gives the ACLA one more powerful card to play in its ongoing negotiations with CMS for PAMA relief.

The same is true of the LAB ACT, a proposed bipartisan measure in the House of Representatives to delay the next round of PAMA data reporting for one year to give labs required to report enough time to do so.

3. The Genetic Testing Crackdown

The year's biggest story in lab-related Medicare fraud enforcement was Operation Double Helix, a massive takedown carried out in five federal districts targeting genetic testing labs and telemedicine companies involved in a $2.1 billion genetic billing fraud scam, one of the largest in Medicare history. The 35 defendants allegedly capitalized on the fears of elderly Americans to by using recruiters to induce them to sign up for unnecessary or non-existent cancer screening tests ordered by doctors who received kickbacks for the referrals. In June, three months before the

NIR

Glenn S. Demby,
Executive Editor

Barbara Manning Grimm,
Managing Editor

Andrea Stowe,
Business Development

Jim Pearmain,
General Manager

Pete Stowe,
Managing Partner

Mark T. Ziebarth,
Publisher

National Intelligence Report
(ISSN 2332-1466) 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.

announcement of the operation, the OIG issued an alert warning Medicare beneficiaries about such genetic testing schemes.

4. The Scary New CMS Medicare Affiliates Exclusions Rule

In a very quiet way that few noticed, CMS dramatically expanded its Medicare and Medicaid exclusion powers to include authority to revoke the enrollment of providers or suppliers that are currently or have in the last five years been affiliated with targeted "bad actors." One of the key parts of the Final Rule, which was issued in September and took effect in November, is an "affiliations" provision that allows CMS to bar individuals and organizations that affiliate with those who pose an "undue risk" of committing fraud, waste or abuse based on their *relationships with other previously sanctioned entities*.

Practical Impact: Labs and other providers can now be held liable not simply for what their principals, employees and business affiliates do while working at the lab but also for what they did during the lookback period, i.e., the five years before they came to your organization. Labs also have to provide disclosure about their business dealings with affiliates. Adding to the scary effect is the broad definition of "affiliates" to include individuals and entities that:

- Have a direct or indirect ownership of 5% or more in another organization;
- A general or limited partnership interest, regardless of the percentage;
- An interest in which an individual or entity "exercises operational or managerial control over, or directly conducts" the daily operations of another organization "either under direct contract or through some other arrangement"
- Act as an officer or director of a corporation; or
- Have any reassignment relationship with the organization.

5. EKRA Casts New Kickback Doubts on Existing Lab Marketing Arrangements

An opioid drug-related law passed in 2018 cast a long shadow on lab marketing arrangements in 2019. The Eliminating Kickbacks in Recovery Act of 2018 (EKRA) provides for penalties of up to $200K and 10 years in prison for knowingly and willfully:

- Soliciting or receiving any remuneration in return for referring a patient to a lab; or
- Paying or offering any remuneration to induce a referral of an individual, or in exchange for an individual using the services of a lab.

Of course, these things are also illegal under existing kickback laws. But EKRA has different exceptions. Result: Lab marketing and business arrangements that meet Anti-Kickback Law and Stark exceptions and

Continued on page 4

The Year in Labs Regulation: The 6 Biggest Stories of 2019, *from page 3*

safe harbors may still violate EKRA. Adding to the problem is that unlike the AKS and Stark, EKRA applies to not only government but private payor arrangements. When EKRA was adopted, the expectation was that the government would issue guidelines to clarify these and other issues surrounding the law in early 2019. But it still hasn't happened.

6. Continued Uncertainty Over FDA LDT Regulation

2019 witnessed no dramatic new developments in the effort to create workable regulations for development of Laboratory Developed Tests (LDTs). What began as an FDA initiative has moved to Congress starting with a bi-partisan bill called the Diagnostic Accuracy and Innovation Act (DAIA) proposing to remove diagnostic tests from the definition of a medical device (and thus outside the purview of the FDA's 510(k) process for medical devices) and establishing a new system for regulating in vitro clinical tests (IVCTs). The FDA countered with a proposal that would keep LDTs within the 510(k) framework but modernize predicate device performance criteria and create an alternative 510(k) pre-certification pathway for certain "well-understood" product types.

The original sponsors of DAIA then incorporated the FDA's ideas, including the pre-certification program concept, into a new bill called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act. Unlike DAIA, the VALID Act makes FDA's authority to regulate IVCTs, and therefore LDTs, explicit. The aim is to establish a framework for overseeing IVCT's at the FDA. The next step, which may happen in 2020, appears to be the proposal of an updated VALID 2 outlining a pre-certification process. But progress remains frustratingly glacial.

FDA Watch: FDA Resounds the Alarm on Biotin Test Interference

In early November 2019, the FDA undated a previous safety communication about the potential of biotin to significantly interfere with diagnostic tests. The update reiterates the warning to lab personnel, diagnostic test developers, providers and patients that biotin can lead to incorrect lab test results.

Biotin Blinding

Biotin, or Vitamin B7, is a water-soluble vitamin commonly used as an ingredient in multi-vitamins, prenatal vitamins and dietary supplements marketed for hair, skin and nail growth. Because biotin bonds with specific proteins that can be measured to detect certain health conditions, many lab tests rely on biotin-detection based methods and technology. The problem is that biotin can distort lab test results leading false highs and false lows, especially when tested patients consume high levels of biotin.

And such high consumption is far from abnormal given how much of it producers use. Thus, for example, dietary supplements may contain up to 650 times more biotin than recommended daily values.

FDA Reaction to Biotin Interference

In 2017, the FDA issued a safety communication addressing biotin interference with certain *in vitro* diagnostic tests and has since issued recommendations for lab personnel and test manufacturers to minimize the potential for interference. The FDA expressed specific concern about biotin interference resulting in falsely low levels of troponin—the biomarker that aids in diagnosis of heart attacks. Misleading diagnoses as a result of incorrect lab results could lead to potentially serious clinical implications, the FDA cautioned.

Since the 2017 safety communication, some lab test developers have been successful at minimizing biotin interference of their assays, according to the updated safety communication, but others have not yet addressed it. The troponin problem remains of particular concern as the FDA continues to receive adverse events reports indicating that biotin interference caused falsely low troponin results.

Recommendations for Providers

The newly revised communication lays out recommendations for providers to minimize the risk of biotin interference, including:

- Discussing biotin and multivitamin supplements with patients;
- Notifying labs if patients being tested are taking biotin;
- Considering biotin interference as a source of error if lab test results don't match clinical presentation; and
- Reporting to the laboratory manufacturer and FDA if they become aware of patients experiencing adverse events following potentially incorrect lab test results due to biotin interference.

Recommendations for Labs

The communication also recommends that labs and testing personnel:

- Be aware that it's difficult to identify samples that contain biotin if assays are used with biotin technology, and to communicate with health care providers and patients to prevent incorrect test results;
- Ask patients if they're taking biotin or a biotin-containing supplement when collecting samples;
- Educate health care providers about biotin interference with lab tests;
- Understand that biotin levels higher than the recommended daily allowance of .03 mg may cause significant interference with lab tests;
- Be aware that specimens collected from patients taking high levels of biotin may contain more than 100 ng/mL biotin;

Continued on page 6

FDA Watch: FDA Resounds the Alarm on Biotin Test Interference, *from page 5*

- Recognize that currently available data is insufficient to support recommendations for safe testing using affected tests in patients taking high levels of biotin, including about the length of time for biotin clearance from the blood;
- Communicate with the lab test manufacturer if there are questions about biotin interference; and
- Be aware of certain troponin assays where the risk of biotin interference hasn't yet been addressed.

Recommendations for Lab Manufacturers

Last but not least, the communication calls on lab test manufacturers and developers to:

- Contact the FDA to discuss biotin interference if an assay uses biotin technology;
- Investigate interference from biotin (up to at least 1200 ng/mL biotin) in assays that use biotin technology and determine the lowest concentration of biotin that may cause clinically significant interference with test(s);
- Communicate to customers that may be unaware that a test uses biotin technology and how it may be affected; and
- Contact the FDA with any questions about biotin technology and interference.

Enforcement Trends: Increase in OIG Fraud Recoveries Belies Continued Decline in Enforcement Actions

OIG fraud recovery has been a solid growth business for nearly two decades. So, when the agency announced a decline in FY 2018 recovery figures, it was more than a bit surprising. But things got back to normal this year, as far as recoveries go. Even so, exclusions and especially civil actions continue to fall. Here are the key findings from the OIG's new Semiannual Report to Congress summarizing enforcement activities for FY 2019.

2019 OIG Fraud Enforcement by the Numbers

After last year's decline from $4.13 billion to $3.43 billion, total OIG health care fraud investigative recoveries topped $5 billion in FY 2019. The agency also expects to recover another $819 million from audits. While total criminal actions also increased (from 764 to 809), they didn't surpass FY 2017 levels the way total recoveries did.

Meanwhile, two other metrics that declined in FY 2018 continued to fall this year, with exclusions dropping from 2,712 to 2,640 and civil actions

dropping even more precipitously from 813 to 695. However, look for exclusions to bounce back now that CMS' affiliations exclusion rule is in effect. (See the related story on page 8).

OIG Enforcement Year Over Year Enforcement Action

Metric	2019	2018	2017
Expected investigative recoveries	$5.04 billion	$3.43 billion	$4.13 billion
Criminal actions	809	764	881
Civil actions	695	813	826
Exclusions of individuals and entities	2,640	2,712	3,244

Labs in the OIG's Crosshairs

The Report also lists enforcement actions involving labs among its top accomplishments for the year, most notably OIG's involvement in Operation Double Helix, the first-of-its-kind multidistrict federal investigation targeting a $2.1 billion cancer genetic testing (CGx) fraud scheme. In September 2019, OIG and Federal and State law enforcers announced the laying of criminal charges against 35 defendants, including nine doctors and individuals associated with telemedicine companies and cancer genetic testing labs, who took part in a massive scam involving payment of kickbacks for referrals of medically unnecessary CGx tests.

(See the related story on page 9).

Top 12 HHS Management & Performance Challenges

1. Curb Opioid Epidemic
2. Ensure Medicare Program Integrity
3. Ensure Medicaid Program Integrity
4. Ensure Integrity in Managed Care and Other Programs Delivered via Private Insurers
5. Protect Health and Safety of Vulnerable Populations
6. Improve Financial and Administrative Management and Reduce Improper Payments
7. Protect Integrity of Public HHS Grants
8. Ensure Safety of Food, Drugs and Medical Devices
9. Ensure Program Integrity and Quality in American Indian and Alaska Native Populations Programs
10. Protect HHS Data, Systems and Beneficiaries from Cyber Threats
11. Ensure HHS Prescription Drug Programs Work as Intended
12. Ensure Effective Preparation and Response to Public Health Emergencies

Genetic Testing: CMS Proposes Expanding NGS Testing Eligibility

In a reversal, CMS is now proposing to cover FDA-approved or -cleared germline NGS testing for breast and ovarian cancer patients who have risk factors that suggest they should receive testing to assess their inherited risk for these cancers.

The NGS Testing Coverage Sage

Approximately 9% to 24% of women with ovarian cancer carry germline mutations in BRCA1 and BRCA2. Germline NGS testing of BRCA1/2 genes can provide information important for preventative screening and surgical interventions. The current Medicare coverage problem began last year when CMS directed Medicare Administrative Contractors (MACs) to align their genetic testing local coverage determinations (LCDs) with a National Coverage Determination (NCD) for next-generation sequencing for advanced cancer patients. At the time, the policy was thought to be restricted to NGS panels used to detect somatic mutations driving patients' cancer and to personalize treatment. So, Palmetto GBA revised a local coverage determination for BRCA1 and BRCA2 genetic testing to restrict coverage for NGS panels when performed in individuals with early-stage disease.

Labs, patient advocacy organizations and professional societies objected and contended that restricting coverage would be harmful to patients. CMS then reopened the NCD, and heard numerous comments from stakeholders.

The New NCD

In the new proposals, CMS proposes that the evidence is sufficient to expand coverage of Next Generation Sequencing (NGS) as a diagnostic laboratory test when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the patient has:

- Ovarian or breast cancer;
- Clinical indications for germline (inherited) testing;
- Risk factors for germline (inherited) breast or ovarian cancer; and
- Not been previously tested using NGS.
- The diagnostic laboratory test using NGS must also:
- Have FDA approval or clearance;
- Be for an FDA approved or cleared indication for use in that patient's cancer; and
- Generate results provided to the treating physician for management of the patient using a report template to specify treatment options.

Additionally, other MACS may determine coverage of other NGS as a diagnostic laboratory test when performed in a CLIA-certified laboratory, when ordered by a treating physician, when results are provided to the

treating physician for management of the patient and when the patient has:

- A cancer diagnosis other than breast or ovarian cancer;
- Clinical indications for germline (inherited) testing,
- Risk factors for germline (inherited) cancer other than inherited breast or ovarian cancer; and
- Not been previously tested using NGS.

What's Next?

Stakeholder comments closed at the end of November and CMS is slated to finalize the NCD on Jan. 27, 2020.

SCORECARD: OIG ENFORCEMENT ACTIONS AGAINST LABS IN 2019

Labs remain at the top of the OIG's enforcement hit list, as illustrated by the number of cases involving labs cited in the agency's new Semiannual Report to Congress for FY 2019:

- False Billing of CGx Tests: OIG participated in Operation Double Helix, the multidistrict federal/state takedown targeting genetic testing labs, telemed companies and doctors involved in a massive $2.1 billion consumer CGx testing scam;
- Medically Unnecessary Tests: Boston Heart Diagnostics paid nearly $1.729 million to settle claims of encouraging physicians to order 26 kinds of medically unnecessary lab tests that were subsequently billed to Medicare, Medicaid and TRICARE;
- Travel Allowances: OIG auditors concluded that Wisconsin Physician Service paid $353.7K in phlebotomy travel allowances for lab tests with miscalculated prorated mileage, incorrect lab fee schedule rates and/or without necessary documentation supporting payment;
- Reference Testing: CRC Health and its parent Acadia paid $17 million to settle charges of billing West Virginia Medicaid for moderate- to high-complexity tests performed by reference labs as if they were performed by CRC outpatient drug treatment centers, even though those centers didn't have proper CLIA certification to perform those tests;
- SVT Billing: The largest in a series of settlements for improperly billing Specimen Validity Testing, which unlike the associated urine drug test it's performed for, is not covered by Medicare, was the $1.346 million paid by Ethos Laboratory in Kentucky; and
- Processing Fee Kickbacks: The $102.2K paid by Midland Medical, Inc. of Florida, one of several labs that settled claims of accepting kickbacks in the form of blood specimen "process and handling" from HDL and Singulex.

Hospital Labs: CMS Pushes Forward with Controversial Price Transparency Rules, *from page 1*

their care. CMS's response to the order was a July 2019 proposed rule requiring hospitals to post gross charges, i.e., list prices, to the hospital's negotiated price by specific payer and plan for a set of "shoppable" services, starting on Jan. 1, 2020. Such services included anything that could be scheduled by a patient in advance. (For more on the proposal, see *National Intelligence Report (NIR)* Sept. 30, 2019.) After pushback from both providers and payors, CMS decided to take the Jan. 1, 2020 active date off the table in early November.

But now CMS has decided to move forward with the rules, effective Jan. 1, 2021, thus granting hospitals a one-year reprieve. Specifically, CMS wants hospitals to provide patients with clear, accessible information about their standard charges for the services. In addition to empowering consumers to comparison shop, the idea is to protect against surprise billing. and compare across hospitals, as well as mitigating surprises.

The Final Rule

In a nutshell, the final rule requires hospitals to disclose negotiated rates and provide patients with accessible information about standard charges. This includes making all standard charges available in a single data file that can be read by other computer systems. Hospitals must also make information about "shoppable services", procedures which can be scheduled by patients in advance, available in a "prominent location online" and describe the information in plain language. More specifically, the final rule will require hospitals to make their standard charges public in two ways, beginning in 2021:

1. Comprehensive Machine-Readable File

Hospitals must make public all hospital standard charges (including the gross charges, payer-specific negotiated charges, the amount the hospital is willing to accept in cash from a patient, and the minimum and maximum negotiated charges) for all items and services on the internet in a single data file that can be read by other computer systems. The file must include additional information such as common billing or accounting codes used by the hospital, such as Healthcare Common Procedure Coding System (HCPCS) codes and a description of the item or service to provide common elements for consumers to compare standard charges from hospital to hospital.

2. Consumer-Friendly Display of Shoppable Services

Hospitals must also make public payer-specific negotiated charges, the amount the hospital is willing to accept in cash from a patient for an item or service, and the minimum and maximum negotiated charges for 300 common shoppable services in a manner that is consumer-friendly and update the information at least annually. Shoppable services are services that can be scheduled by a healthcare consumer in advance such as X-rays,

outpatient visits, imaging and laboratory tests or bundled services like a cesarean delivery, including pre- and post-delivery care. In addition:

- The information must be made public in a prominent location online;
- The information must easily accessible, without barriers and searchable;
- Item and service descriptions must be in "plain language"; and
- Shoppable service charges must be displayed and grouped with charges for any ancillary services the hospital customarily provides with the primary shoppable service.

To ensure that hospitals comply with the requirements, the final rule provides CMS with new enforcement tools including monitoring and auditing as well as the authority to impose corrective action plans and civil monetary penalties of $300 per day.

Proposed Rules for Payers

To cover its flank, the agency also included a proposed rule requiring health plans to disclose on a public website their negotiated rates for in-network providers and allowed amounts paid for out-of-network providers. The Transparency in Coverage proposed rule requires employer-based group health plans and health insurance issuers offering group and individual coverage to disclose price and cost-sharing information to participants, beneficiaries, and enrollees up front. If finalized, the proposed rule would require health plans to:

- Give consumers real-time, personalized access to cost-sharing information, including an estimate of their cost-sharing liability for all covered healthcare items and services;
- Provide that access via an online tool (as well as in paper form, if consumers request it) available to all members of group health plans; and
- Disclose on a public website their negotiated rates for in-network providers and allowed amounts paid for out-of-network providers.

The proposed rule would also encourage health insurance issuers to offer new or different plan designs that incentivize consumers to shop for services from lower-cost, higher-value providers by allowing issuers to take credit for "shared savings" payments in their medical loss ratio calculations.

The Industry Strikes Back

Payer and provider stakeholders responded to the final and proposed rules with a chorus of boos and promises of litigation. In a joint statement, the American Hospital Association, Association of American Medical Colleges, Children's Hospital Association, and Federation of American Hospitals called the proposed rule "a setback in efforts to provide patients

Continued on page 12

Hospital Labs: CMS Pushes Forward with Controversial Price Transparency Rules, *from page 11*

with the most relevant information they need to make informed decisions about their care." On Dec. 4, the organizations joined with member hospitals to file a lawsuit claiming that mandatory price disclosure will confuse patients, thwart competition and innovation, violate their First Amendment rights and exceed the Administration's authority.

Impact on Labs

In addition to imposing new administrative burdens and restrictions on what hospital and other labs can charge, providers cite concerns about mandatory pricing disclosure's unforeseen adverse impact on patient relations and expectations.

1. Damage Due to Disconnect between Quoted & Actual Charges

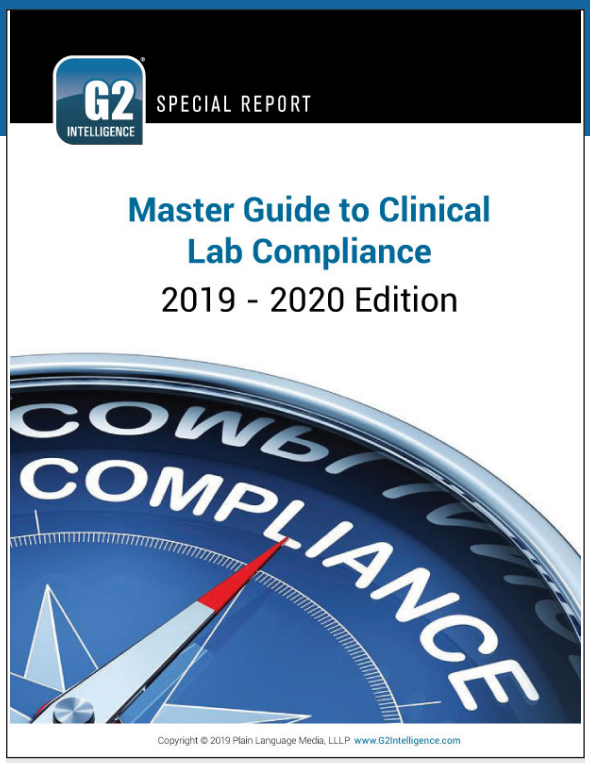
Standard charges are based on customary care and don't take into account emergency or acute situations. In other words, standard pricing assumes a best-case scenario which doesn't always prove to be realistic. This puts labs in a ticklish position when actual patient charges end up being higher than the previously quoted prices. The potential result is damage to not only customer relations but the trust on which the patient relationship is based.

2. Demand for Medicare Payment Information

The standard charges referred to in the CMS proposal are provider charges only. They don't take into account what Medicare pays for the service. But if providers begin disclosing this information, patients may also expect and insist on receiving Medicare payment information as well.

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
- Rules and Regulations
- False Claims Act
- Anti-Kickback Laws
- Stark Laws
- "*Qui tam*" provisions
- Anti-retaliation provisions
- FCA enforcement actions
- Billing Practices
- Contract Sales Agreements
- Registry Payments
- Lab/Physician Relationships
- Gifts
- **And Much More!**

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**