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INSIDE THIS ISSUE

New Laws: Proposed Kickback Changes Would Provide Needed Relief But Also Largely Exclude Labs

In what could be the most significant story in health care fraud and abuse compliance of the past several years, the CMS and OIG proposed new rules (the Proposal) to adapt 20th century kickback laws to 21st century market conditions, as well as tie up loose ends, inconsistencies and lacks of clarity that have hamstrung deal making by not only labs but all health care players. The new rules, issued on Oct. 9, 2019, are long-awaited and very, very necessary. But they're also very, very long—386 pages to be exact. And they're heavy reading for even the most seasoned of lab compliance managers. So, in case you don't have the time or desire to hack your way through the whole document—or the resources to hire an attorney to do it for you—you can use this overview to orient yourself.

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Medicare Reimbursement: CMS Eases Coverage Restrictions on NGS Testing of Early-Stage Cancer Patients

After years of resistance, CMS is now prepared to pay for germline (inherited) next-generation sequencing (NGS) testing of Medicare early-stage cancer patients under certain conditions. Here's a look at the new national coverage determination (NCD) that the agency proposed on Oct. 29, 2019.

The CMS About-Face

We've now come full circle. At the start of 2019, CMS issued an NCD instructing Medicare Administrative Contractors (MACs) to apply coverage limitations on use of NGS test panels to detect somatic mutations of advanced cancer patients to germline testing of early-stage cancer patients. The new and unexpected coverage cutback provoked an outcry among testing labs and cancer

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Proposed Kickback Changes Would Provide Needed Relief But Also Largely Exclude Labs, *from page 1*

The Bittersweet for Labs

Although the proposal does offer real kickback relief, it also excludes labs from many of the most important new exceptions, including those covering value-based care, EHR and cybersecurity.

New Kickback Rules Are a Long Time in the Making

The principle that providers must make medical decisions based on patient needs without being influenced by bribes or inducements remains as sound as the day these laws came into being. The problem is that the laws haven't undergone major change in over three decades. During this time, the market the laws are designed to regulate have changed almost beyond recognition. And kickback laws crafted for fee-for-services just don't work in today's value-based care models where care is coordinated to improve efficiency, care quality and health outcomes. Value-based care often calls for providers to make arrangements that, while innocent in intent and essential to efficiency, but raise red flags under the kickback laws. The resulting liability risks chill desperately needed innovation.

The culmination of years of discussion, the new proposal is the federal government's first systematic effort to fix the disconnect between the modern market and the antique kickback laws. It also goes beyond value-based care by addressing other newfangled issues adversely affected by the kickback laws including cybersecurity, the electronic health record (EHR) and accountable care organizations (ACOs).

The 3 Parts of the Proposal

The Proposal suggests revisions to three different kickback laws:

- The Stark Law (Stark), which bans physicians from referring patients to entities with which they or immediate family members have a financial relationship;
- The Antikickback Statute (AKS), which bans physicians and other providers from accepting bribes or other renumeration in exchange for generating business through Medicare, Medicaid or other federal health programs; and
- The Civil Monetary Penalties law (CMP law), which bans providers from inducing beneficiaries to use their services.

Labs Excluded from the New Value-Based Arrangement Rules

First, the bad news. The proposed changes allowing for value-based (VB) care arrangements don't apply to labs. Adding insult to injury is CMS' explanation for excluding labs: "On the basis of our historical enforcement and oversight experience, we are concerned that [some labs], which are heavily dependent upon practitioner referrals, might misuse the proposed safe harbors primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means

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to create value for patients and payors by improving the coordination and management of patient care." Besides, CMS adds, labs aren't on "the front line of care coordination and treatment decisions" the way physicians and hospitals are.

The Other Excluded Providers

Labs aren't the only ones left out. The proposed new definition of participants who can participate in so-called value-based enterprises also excludes pharmaceutical manufacturers as well as manufacturers, distributors or suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS).

But don't be too disappointed. Attorney **Kristen Carter** of Baker Donelson stresses that these are just proposed rules and that nothing is definite yet. Labs that are interested in participating in VB arrangements may want to comment on the Proposal, she says. The other bit of good news is that labs can take advantage of the other proposed new exceptions, which we'll discuss below.

The 8 Key Changes

1. New Stark Exceptions for VB Arrangements

The Proposal would create new exceptions to Stark bans for five VB payment models available to providers other than labs, pharma manufacturers and DMEPOS:

1. Full financial risk, as long as risk is prospective and there are no additional payments covering the cost of patient care, e.g., global budgets or capitated payments based on predetermined rates;
2. VB arrangements with meaningful downside financial risk, defined as when a physician is responsible for paying "no less than 25% of the value of the remuneration the physician receives" for failing to meet the specified benchmarks;
3. VB arrangements regardless of risk level, which would allow physicians to enter into VB arrangements, even if they only assume upside risk;
4. Indirect compensation arrangements, where the compensation doesn't involve a direct transaction between the payor and provider; and
5. Price transparency, in which patients will know in advance how much they'll be expected to pay.

2. New AKS Safe Harbors for VB Arrangements

Parallel to the Stark exceptions, the Proposal lists three new AKS safe harbors for VB arrangements, all of them which would exclude labs, pharma manufacturers and DMEPOS:

1. Coordination arrangements to improve quality, health outcomes and efficiency;

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Proposed Kickback Changes Would Provide Needed Relief But Also Largely Exclude Labs, *from page 3*

2. VB arrangements with substantial downside financial risk; and
3. VB arrangements with full financial risk.

3. New Exception/Safe Harbor for Cybersecurity Donations

Current Stark exceptions and AKS safe harbors allow providers—other than labs—to donate EHR products and services to physicians for purposes of interoperability. CMS is proposing to expand the scope of the Stark EHR exception and establish a new AKS safe harbor to cover cybersecurity products and services. To qualify for the exception/safe harbor:

- The donation must be made under a written agreement;
- The donated products/services must be certified as interoperable and not equivalent to products/services the physician already has; and
- The physician must contribute 15% of the donor lab's costs.

The bad news is that labs wouldn't be able to benefit from the new cybersecurity rules. The good news is that CMS indicated its willingness to listen to the case for letting labs into both the current EHR and new cybersecurity rules. Are we being too suspicious, the Proposal asks. That's why it's so important for labs with a stake to comment on the Proposal.

4. New AKS Safe Harbor for Patient Engagement Arrangements

Another proposed new AKS safe harbor would allow for patient engagement and support arrangements to improve quality, health outcomes and efficiency. But once again, the Proposal would cut out labs, pharma companies and DMEPOS, unless the comments persuade CMS to revise its terms.

5. New Definitions Making Stark Exceptions Easier to Use

Although labs are cut out of most of the proposed new VB arrangement and other Stark exceptions and AKS safe harbors, they stand to benefit from the new clarification the Proposal provides on terms and rules that providers must meet to qualify for other Stark exceptions, including those for arrangements:

- Providing "commercially reasonable" compensation: CMS is proposing two possible definitions of "commercially reasonable": (i)"the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements"; or (ii) "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty";
- In which compensation isn't based on volume or value of referrals: The Proposal suggests that compensation would not meet that criterion if:

- It uses a mathematical formula that includes referrals or other business generated as a variable; and
- The compensation amount correlates with the number or value of a physician's referrals to an entity;

- In which compensation reflects fair market value: The Proposal would redefine this critical term to match the definition that applies to the exception for equipment or property rentals, i.e., the "value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction."

6. Elimination of Stark "Period of Disallowance" Waiting Period

Under current rules, if an arrangement between a physician and a lab (or other provider) doesn't meet the requirements of a Stark exception, the physicians must refrain from making referrals to the labs and the lab must refrain from billing Medicare for referred services during a "period of disallowance" after the relationship ends. CMS calls the period of disallowance rule as "impractical and overly prescriptive" and is proposing to eliminate it in favor of a case-by-case assessment depending on the particular relationship involved.

7. Expansion of 90-Day Grace Period for Stark Exceptions

To use a Stark exception, the physician and lab are required to sign the documents subject to a 90-day grace period that applies as long as the parties comply with all the underlying requirements. The Proposal would expand the rule allowing the parties to defer not only signing but executing the required documents for the 90 days.

8. New Annual $3,500 Stark Exception

The Proposal includes a new exception for arrangements in which a lab pays a physician less than $3,500 in a calendar year in exchange for items or services. This proposed exception doesn't require a writing, signature or that the compensation be set in advance. Nor does it ban either or both parties profiting from the deal. But it does require that:

- The physician actually provides the services or items the compensation covers;
- The arrangement furthers a legitimate business purpose;
- The terms and conditions are similar to like arrangements;
- The remuneration isn't based on the value or volume of referrals; and
- The remuneration reflects fair market value for the items or services.

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Proposed Kickback Changes Would Provide Needed Relief But Also Largely Exclude Labs, *from page 5*

Takeaway: The Need for Labs to Engage

Sadly, the Proposal reaffirms that the OIG's inveterate suspicion of the lab industry remains. Barring labs from taking advantage of Stark and AKS relief to participate in VB arrangements would hurt not only labs and providers. Excluding labs from EHR interoperability and cybersecurity arrangements is even more puzzling.

The good news is that there's still time to right these wrongs. It can't be overemphasized that the Proposal is just that, a proposal. The agencies are quite candid throughout the Proposal, freely admitting that they don't trust labs and calling on stakeholders to weigh in and try to change their mind before the comment period ends on Dec. 31, 2019.

***Bottom Line:** The lab industry has a unique and crucial opportunity to dispel old prejudices and make its case for being allowed into the VB care and cybersecurity arrangements that will define medicine in the decades to come.*

At A Glance: The 4 Things Labs Must Know

1. CMS and OIG are providing significant Stark/AKS relief for value based care arrangements but want to exclude labs
2. The same is true for EHR interoperability and cybersecurity relief
3. Between now and December 31, the agencies will take comments on whether to let labs in on the Stark/AKS relief
4. Meanwhile, some of the proposed Stark changes, including clarified definitions of crucial terms needed for exceptions, will help labs

Laboratory Developed Tests: Hopes that Congress Will Table VALID by the End of 2019

The lab industry, FDA and Congress have been collaborating on legislation that would create something very badly needed: a separate system outside the Section 510(k) premarket review framework for medical devices that makers of lab developed tests (LDTs) and in vitro diagnostic (IVD) kits can use to bring their products to market. After years of fits and starts, current hopes reside in a proposal called the *Verifying Accurate, Leading-edge IVCT Development Act* (VALID). Here's a look at where things stand with VALID. **Bottom Line:** VALID remains on course but is still in the early conception stages.

VALID's Current Status

At this time, VALID is basically a discussion draft, says **Tom Sparkman**,

Vice President, Government Affairs at the American Clinical Laboratory Association (ACLA). "We don't view it as a finished product by any means," says Sparkman. The current VALID proposal would create a new diagnostic-specific framework overseen by the FDA while leaving CMS to regulate lab operations under the Clinical Laboratory Improvement Amendments (CLIA).

Things are still in the negotiation stage at this point. The lab industry, diagnostic manufacturers and patient advocates all seem supportive of establishing such a scheme but have differing views on how to do so. There have been a series of stakeholder meetings to discuss the proposal.

What's At Stake

The need for a workable LDT solution is the one thing that all sides agree on. As Sparkman explains, the laws and regulations adopted decades ago haven't kept pace with the significant leaps made in diagnostic science, technology and genomic testing. ACLA says that regulators have failed to deliver the desperately needed clear guardrails to innovators and assured paths for patient access. In addition to relying on outdated rules, federal and state regulators have begun to overlap and create unnecessary burdens, duplication and even confusion. "This overlap and confusion threatens to stifle continued medical diagnostic progress," says Sparkman.

The Good & Bad of VALID

The lab industry sees both good and bad in VALID. While there's concern that the FDA proposal affords the agency too much discretion, the industry is encouraged by the idea of a pre-certification process. Pre-certification has promise, says Sparkman, but the regulatory burden must be proposed in the current draft is too onerous and needs to be lightened.

Sparkman also suggests that the currently drafted VALID lacks clarity in drawing lines between any new FDA authority and CLIA. The industry, he points out, would continue to be regulated by CMS, and conflicting or overlapping CMS and FDA regulatory requirements would impede innovation and patient access. The lab industry also wants certainty that grandfathered tests would not have to go through new regulatory approvals and thereby deprive patient access to clinical tools that have been available for years.

What Next?

The next stage in the process is to update the draft and introduce the bill. VALID has four sponsors—two in the Senate and two in the House—who see VALID as a sensible, risk-based approach towards regulation of IVDs/LDTs that should become a legislative priority. The hope is to introduce the next draft of the bill in late 2019. But that's far from a sure thing. In the meantime, we'll keep an eye on things and let you know what happens.

New Product Development: FDA Issues Final Guidance on IVD Oncology Trials

On Oct. 10, 2019, the FDA finalized guidance on an optional streamlined submission process to determine whether use of an investigational in vitro diagnostic (IVD) in an oncology clinical trial is considered significant risk, nonsignificant risk, or exempt from investigational device exemption requirements. Entitled the "Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination," the guidance was developed by the FDA Oncology Center of Excellence.

The New Streamlined Submission Process

Typically, IVD tests used in investigational cancer drug trials require two submissions: one for the IVD test and another for the drug. The final guidance allows companies to submit for simultaneous review for the clinical trial. The new streamlined process is optional but the FDA "encourages sponsors to use it. . . when possible to reduce administrative burden on sponsors and FDA and to maintain the current level of regulatory approval." Sponsors should submit to the Center for Devices and Radiological Health (CDER) or Center for Biologics Evaluation and Research (CBER) all information about the oncology codevelopment program (including information about the investigational IVD) in the trial protocol for the investigational new drug application (IND).

One sponsor should take the lead in communicating with FDA about the IND, says the final guidance. To indicate its intent to use the streamlined process, the sponsor should include the text "Streamlined IVD SRD" in either:

- In Section 11 (under "Other") of the Form FDA 1571, Investigational New Drug Application; or
- The cover letter it submits with the IND (along with a reference to which section(s) of the electronic common technical document contains relevant information).

IVD Information to Include in Submission

The final guidance also lists the additional information about the IVD and how it will be used in the trial that the sponsor should list in the protocol it submits for the IND, including:

- A description of the device;
- How the results from the investigational IVD will be applied in the clinical trial;
- A description of the population and information regarding what is known about the prevalence of the biomarker (evaluated by the investigational IVD) in the patient population;

- The specimen type that will be collected for investigational IVD testing (including the anatomical site) and whether any biopsy conducted exclusively for investigational IVD testing could present a potential for serious risk to the health, safety or welfare of the subject.

By signing Form FDA 1571 (section 17) sponsors provide assurance of an institutional review board review of the complete clinical trial protocol and activities for the investigational IVD and the investigational drug, the final guidance specifies.

The CBER or CDER will then use the information to determine as part of the IND review and within the 30-day review period whether use of the IVD is significant risk (SR), nonsignificant risk (NSR) or exempt from investigational device exemption (IDE) requirements.

Determination	Consequence
NSR	CBER or CDER confirms determination in appendix to Study May Proceed Letter + reminds sponsor to follow NSR procedures in obtaining biopsies for testing + submit unanticipated adverse device effect reports to IND
SR	CBER or CDER confirms determination in appendix to Study May Proceed Letter + asks sponsor to submit IDE application to CBER or Center for Devices and Radiological Health (CDRH) + not start trial until after IDE is approved
Exempt	CBER or CDER confirms determination in appendix to Study May Proceed Letter

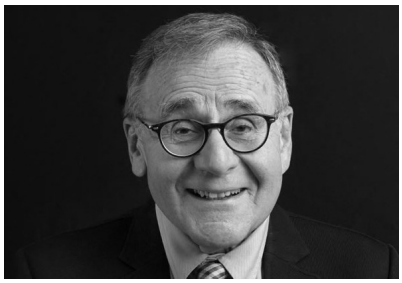
Global News: EU Delays Launch of Eudamed Database

The European Commission (EC) is delaying the launch of the European database on Medical devices (aka Eudamed) until May 2022. Originally, manufacturers were supposed to be compliant by May 2020 with the new Medical Device and In Vitro Diagnostic Regulations, but technical challenges forced the delay.

According to a statement published online, the EC will continue to work on implementing the database, but concluded that it will "only be possible to make Eudamed operational once the entire system and its different modules have achieved full functionality and have been subject to an independent audit." The date of application of the MDR remains May 2020, and medical device manufacturers are expected to collect the necessary data and enter into Eudamed once available.

Kellison Public Service Award: Kellison and G2 Intelligence Honor Dr. Sidney Goldblatt

Dr. Sidney Goldblatt, MD, is the 2019 recipient of the Kellison Public Service Award. Dr. Goldblatt has been founder, medical director and CEO of Molecular Dx; founder and CEO of Goldblatt Systems; founder and expert pathologist for ForensicDx; and founder and CEO of Goldblatt Pathology Associates.



Dr. Sidney Goldblatt, MD

The award recognizes the dedication of his life and career as a medical doctor, pathologist, scientist, and entrepreneur to making health care better and to enable data-driven medical discovery. (Pictured below are **Scott Liff**, president and CEO of Kellison and Company; **Laura Voeghtly**, Chief Scientist at MolecularDx, who accepted the award on behalf of Dr. Goldblatt; and **Jonathan Ziebarth** of G2 Intelligence. The presentation was made at Lab Institute 2019, a conference presented by G2 Intelligence in November in Washington, D.C.)

After graduating from Temple Medical School, Dr. Goldblatt joined the NIH as a researcher. Later, as chairman at Conemaugh Memorial, he worked with the founder of digital equipment corporation to build one of the industry's first laboratory information systems, CliniLab. In 1979, he founded Sunquest Information Systems to enable the creation of clinical laboratory data to support patient care.

To facilitate inter-operability, Sunquest worked with UCSF and OAIS to deliver on the earliest implementation of HL7 transactions. Following the sale of Sunquest in 2001, Dr. Goldblatt began developing a clinical semantic network (CSN) to bring the same data paradigm to electronic medical records. The Clinical Semantic Network grew out of Dr. Goldblatt's work with SNOMED when he was working as the Governor of the College of American Pathologists. Delivered as a patient engagement tool, the CSN allows patients, caregivers, clinicians, and physicians to work together in using data to deliver a new model of health care.

In addition to his work at the CAP, Dr. Goldblatt was a Fellow at the National Cancer Institute where, as head of comparative cytology activities, he led the team creating the cytoanalyzer, automating PAP smear screening. He has also been an administrator and board member of a large community health system. As founder of MolecularDx, he is delivering molecular diagnostics and genomic data to precision medicine. Finally, his dedication to making health care better has also led to the creating of ForensicDx, an advanced forensic science center using technology such as CT and LODOX full body digital imaging, mass spectrometry, and NGS to study potential solutions to the current opioid crisis.

"These activities and accomplishments highlight the incredible passion and dedication Dr. Goldblatt has brought to the lab industry throughout his incredible career," said Kellison's Scott Liff in presenting the award at Lab Institute 2019.

Enforcement Trends: CMS Delays Controversial Hospital Price Transparency Rules

CMS has decided to delay its controversial proposal to require hospitals to post their standard prices based on their negotiated contracts with insurers. But while the delay represents a temporary setback for the agency, the transparency initiative is a long way from dead.

The Transparency Imbroglio

Had it gone through as scheduled, the rule CMS proposed in July 2019 in response to a President Trump executive order, would have extended the new rule requiring hospitals to post their 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 could include anything that can be scheduled by a patient in advance. (For more on the proposal, see *National Intelligence Report (NIR)* Sept. 30, 2019.

After a hailstorm of protest from both providers and payors, CMS has now decided to take the Jan. 1, 2020 active date off the table. "We received over 1,400 comments" on the rule, acknowledged CMS Administrator Seema Varma in a tweet. We intend to summarize and respond to the comments in due time, Varma noted. The agency's new plan: Issue a rule on pricing transparency alongside a more comprehensive proposal for health plan transparency, an RFI for which has already been issued.

Stay tuned.

CMS Eases Coverage Restrictions on NGS Testing of Early-Stage Cancer Patients, *from page 1*

patient advocates. For more on the coverage controversy, see *National Intelligence Report (NIR)* June 17, 2019.

In the proposed NCD, CMS acknowledges that "the evidence for cancers of the breast and ovary suggests that the use of NGS can identify germline mutations which can lead to better stratification of patients in the physician management of inherited cancers of the breast and ovary." Accordingly, CMS says Medicare will cover germline NGS testing of cancer patients to assess their inherited risk for such cancers

The 4 Required Coverage Conditions

The NCD also lists conditions regarding:

1. Who Can Order Tests

First, the tests must be ordered by the treating physician for purposes of managing the patient's treatment. This is standard stuff.

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CMS Eases Coverage Restrictions on NGS Testing of Early-Stage Cancer Patients, *from page 11*

2. Which Patients Can Have the Tests

Tests are covered only if the patient:

- Has breast or ovarian cancer;
- Has clinical indications for germline testing;
- Has risk factors for germline breast or ovarian cancer; and
- Hasn't previously been tested using NGS.

3. Which Tests Can Be Provided

Ordered NGS tests must be cleared or approved by the FDA and the patient must be tested for an indication for which the test has been cleared or approved.

4. Who Can Perform the Tests

Tests must be performed by a CLIA-certified lab and the test results must be furnished to the patient's doctor and indicate treatment options based on the genetic test results.

More Coverage to Come?

The NCD also gives Medicare Administrative Contractors (MACs) to adopt local coverage determinations for NGS germline tests for other cancers in patients with ovarian and breast cancer subject to the same above criteria. Exception: The ordered test would not have to be approved or cleared by the FDA.

Takeaway: The NCD is just a proposal. After getting public comments, CMS is scheduled to finalize the policy on Jan. 27, 2020.

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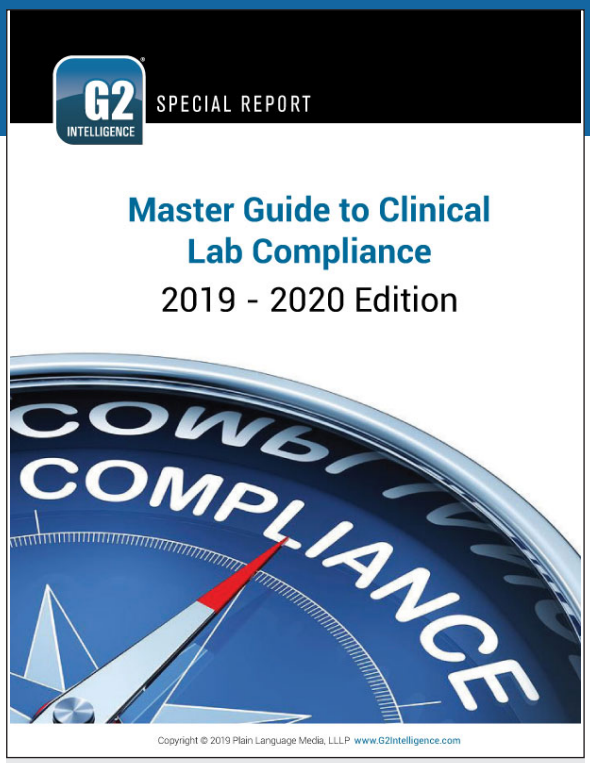

Lab Compliance Essentials **covers:**

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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.

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