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LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

January 2020

INSIDE THIS ISSUE

Compliance Perspectives: New Laws & the Top 5 Challenges Lab Compliance Officers Face in 2020

Labs remain at the forefront of the federal government's suspicious persons list and health care fraud enforcement agenda. But in addition to the customary laws that labs are used to, the government made some new ones in 2019, including scary regulatory requirements that garnered little attention. There were also significant new enforcement policy changes, including with regard to HIPAA. Here's a rundown of what we at G2 Intelligence voted the five most significant new laws that lab compliance managers need to be aware of entering the new year, along with the steps necessary to meet the compliance challenge each one of them creates.

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

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Sales & Marketing: The Perils of Restructuring Sales Commissions for EKRA

For many years, it was fairly common practice for labs to pay their sales representatives variable compensation based on the volume and value of the tests they generated. But those arrangements became problematic under the new Eliminating Kickbacks in Recovery Act of 2018 (EKRA) law. (For more on EKRA, see the related story on page 6.) To avoid the risk of criminal penalties under EKRA, labs had to eliminate these commissions and bonuses from contracts with sales and marketing staff. A recent federal case is an illustration of the kind of complications and backlash this restructuring has the potential to engender.

What Happened

In addition to a monthly base salary, a Hawaii lab paid its senior account reps commissions related to the revenues they and their team supervised brought in. But when EKRA took effect, the lab felt it had no choice but to pay the reps a fixed annual salary and a discretionary bonus determined by the CEO each quarter. Although the result was lower annual

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Compliance Challenge: Massive concern about a law adopted in October 2018 was the biggest story in lab compliance in 2019. The Eliminating Kickbacks in Recovery Act of 2018 (EKRA) provides for criminal penalties of up to $200K and 10 years in prison for knowingly and willfully: i. soliciting or receiving any remuneration in return for referring a patient to a lab; or ii. paying or offering any remuneration to induce a referral of an individual, or in exchange for an individual using the services of a lab. The headline isn't the restriction, which overlaps with current Anti-Kickback Statute (AKS) and Stark Law (Stark) rules but the fact that EKRA lacks the exceptions and safe harbors that apply to those existing laws.

What To Do: Unless and until the DOJ issues guidance or Congress adopts clarifying legislation, lab compliance officers must revisit the arrangements they carefully crafted to meet AKS and Stark to ensure they meet EKRA (including arrangements with private payors since EKRA is an all-payor statute), especially:

- Commissions and variable pay arrangements tied to the value or volume of lab testing generated with marketing, sales, accounting and other representatives;
- Leases of office space between your lab and referring physicians; and
- Participation agreements with Accountable Care Organizations (ACOs).

2. Broad New Medicare Affiliates Exclusions Rule

Compliance Challenge: While EKRA has garnered lots of attention, an even scarier new law has flown under the radar. In November, a new Final Rule took effect giving CMS broad new powers to exclude or deny Medicare enrollment to labs that currently affiliate or have affiliated over the past five years with individuals and organizations that pose an "undue risk" of committing fraud, waste or abuse.

What To Do: Vetting your current principals, employees and business affiliates is no longer enough. To avoid potential exclusion under the "affiliates" rule, you must now do background checks on all affiliates with which your lab has associated during the five-year lookback period to ensure they haven't been excluded from a government health program. The term "affiliate" is defined broadly to include those that have or had:

- A direct or indirect ownership of 5% or more in another organization;
- A general or limited partnership interest, regardless of 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";
- A role as an officer or director of a corporation; or
- Any reassignment relationship with the organization.

LCA

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If you find that affiliates have been excluded or involved in healthcare fraud, you must come forward and disclose it to CMS if the agency requests it. However, disclosure obligations are expected to become more active and waiting for a CMS request won't be good enough.

3. New CMS Exclusion Rules for Not Reporting Minor Infractions

Compliance Challenge: In addition to the "affiliates" provisions, the new November Final Rule allows CMS to exclude labs for failing to report minor state disciplinary offenses committed by advanced practice nurses, therapists, physician assistants and other licensed health professionals they employ.

What To Do: While it probably won't affect the scope of current background checks, labs will have to broaden their CMS reporting and disclosure rules to meet the new rules. Historically, labs only had to report to CMS state board administrative actions that placed restrictions on a licensee, such as licensing suspension or revocation. Now, you'll have to report even minor licensing board actions, e.g., fines or reprimands for failing to timely complete required continuing education courses, or actions settled to avoid the costs of filing an administrative appeal. Moreover, the new rule covers the actions of not only state oversight boards but also:

- Actions of a federal or state health care program;
- Determinations of an Independent Review Organization (IRO); or
- Actions of any other equivalent governmental body or program that oversees, regulates or administers health care providing and that involve underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.

4. Proposed New Kickback Relief Rules

Compliance Challenge: On Oct. 9, 2019, CMS finally revealed its long-awaited kickback reform proposals. And while the proposals do offer substantial relief by creating broad new exceptions for value-based care, EHR, cybersecurity and ACOs, the agency doesn't want to let labs participate in the proposed new exceptions. "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."

What To Do: Lab compliance officers will have to pay close attention to the Final Rule which CMS is expected to publish after responding to the public feedback in January. The key thing to watch for is whether the agency backs down from its proposal to cut out labs from the new exceptions. In either case, there are parts of the proposed rule that benefit labs, including:

- Clarification of "commercially reasonable" compensation for purposes of applying current AKS and Stark exceptions;
- The new definition of "fair market value" for purposes of applying the current exception for equipment or property rentals;

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- The elimination of the current "period of disallowance" waiting period for arrangements between labs and physicians that fail to qualify for a Stark exception;
- The expansion of the 90-day grace period for Stark exceptions, which would allow labs and physicians to not only sign but also execute the required documents during the 90 days; and
- The new exception for arrangements in which labs pay a physician less than $3,500 in a calendar year.

5. The New HIPAA Enforcement Initiative

Compliance Challenge: Historically, HIPAA enforcement has focused predominantly on the failure of labs and other covered entities to keep protected health information (PHI) private and secure. But in March, the HHS Office for Civil Rights (OCR) announced a new enforcement campaign targeting providers that keep PHI too close to the vest by denying patients their access rights. On Sept. 9, 2019, the OCR announced its first action under its so called Right of Access initiative, an $85,000 settlement with a Florida hospital for denying a mother timely access to her unborn child's PHI. OCR struck again on Dec. 12, by announcing another settlement for the same amount with a Florida primary care and interventional pain management firm that failed to forward a patient's PHI in electronic format to a third party.

What To Do: While denying individuals access to their PHI has always been illegal, thanks to Right of Access, it now carries the real risk of fines and other penalties. That makes it imperative for compliance officers to do a full scale review to ensure that IT systems are in place and lab staffers are doing a good job of respecting patients' rights to see, copy and amend their lab records in the requested format and without being overcharged for doing so.

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compensation, the lab felt like the new salary-based structure was a fair arrangement since it would now bear the financial risk of a rep's poor performance. Unfortunately, many of the senior reps were less than happy about losing their revenue-based commissions, not to mention the fact that the deal also required them to sign a new non-compete.

Most dissatisfied of all was Darren, the senior rep serving as the lab's Chief Business Development Officer. The bad blood had been brewing a while. Darren felt he was instrumental in the lab's commercial success and that his contributions weren't appreciated. The resentment grew when the lab rejected his quest for an equity stake. The new salary arrangement was the last straw.

The CEO soon learned that Darren was talking to competitors about

leaving; worse, he was trying to persuade key colleagues to come along with him. She was also convinced that Darren was disclosing secrets about the lab's sales methods to competitors, poaching lab clients and making sexually demeaning remarks about her. Soon major clients began to leave, including those for which Darren was responsible. And why the CEO didn't know why, she suspected that Darren was behind the client exodus.

The lab suspended Darren, apparently wanting to keep him employed to avoid the massive severance payment he'd be due if he was terminated. During the disciplinary proceeding, things got ugly with insults exchanged and Darren threatening to take all of the lab's clients and drive it out of business. The next stage in the escalation was litigation. The lab accused Darren of breach of contract and unlawful disclosure of trade secrets. It also asked for a preliminary injunction barring Darren from competing with the lab until the case was resolved.

The Ruling

The federal court refused to issue the preliminary injunction.

The Reasoning

Courts are reluctant to issue injunctions before a lawsuit and will do it only if the person seeking the injunction can prove that, among other things, it would suffer "irreparable harm" without one. Darren's threat to put the lab out of business was the irreparable harm, the lab contended. The problem, as even the lab acknowledged, was that nothing had actually happened yet. Darren was still on suspension and the court wasn't willing to issue the injunction as a "prophylactic" measure so it could "get ahead of the problem."

It doesn't work that way, the court explained. While threatening to put someone out of business can be the basis for an injunction, the threat has to induce reasonable and realistic fear of imminent and irreparable loss. In this case, there was no reasonable basis to believe that Darren would and could make good on his threat:

- He was still employed by the lab;
- His attempts to persuade the other senior reps not to sign the new sales compensation contract had failed;
- There was no proof that he was responsible for the loss of the lab's clients; and
- There was no proof that the lab incurred any losses as a result of his alleged disclosure of proprietary information to competitors.

S&G Labs Haw., LLC v. Graves, 2019 U.S. Dist. LEXIS 204058, 2019 WL 6311356

Takeaway: Losing a preliminary injunction doesn't mean losing the entire case. The lab still has the chance to prove its claims at trial. And if it does, it may be entitled to an injunction as well as monetary damages.

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But what it can't do is keep Darren from going about his business unless and until it does prevail in court.

The larger significance of the Graves case is in illustrating how compliance-driven changes to sales and marketing compensation arrangements can engender bad feelings, disputes and even litigation with affected staff members. So, it's critically important to ensure that:

- *The reps are aware of what EKRA is and why it may be necessary to alter their bonus and commissions arrangements to comply; and*
- *The reps get fair consideration for giving up their opportunity to earn volume- and/or value-based bonuses and commissions.*

EKRA: More than a Year Out, Major Questions Remain Unresolved

One of the scariest new lab compliance laws in recent memory is the Eliminating Kickbacks in Recovery Act of 2018 (EKRA). While laws banning remuneration in exchange for referrals is nothing new to labs, EKRA is much broader than the Anti-Kickback Statute (AKS) and Stark Law (Stark) that the industry has been dealing with for decades. The scary part is that EKRA is much broader than those laws. Worse, it may cast new doubt on the business, compensation and other arrangements that labs rely on to satisfy AKS and Stark. An arrangement that satisfies AKS and Stark, in other words, may not work for EKRA. The reason for emphasizing "may" and "may not" is that we simply don't know. The law is vague and lacking in implementing regulation. When it came out more than a year ago, the assumption was that the government would offer guidelines and clarification fairly soon. Unfortunately, that hasn't yet happened. And there's no indication of when or even if it ever will.

What EKRA Is All About

EKRA is part of a larger piece of legislation enacted to combat the opioid crisis called the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) that took effect on Oct. 24, 2018. EKRA is the part of the SUPPORT Act that deals with labs and other providers. It imposes penalties of up to $200K and 10 years in prison for paying remuneration to induce or reward referrals to labs, clinical treatment facilities and recovery homes, including knowingly and willfully:

- Soliciting or receiving any remuneration in return for referring a patient to a lab, clinical treatment facility or recovery home; 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, clinical treatment facility or recovery home.

Of course, those things are also problematic under the AKS and Stark. The difference, though, is that unlike the current kickback laws, EKRA is an "all-payor" statute, i.e., it applies not just to Medicare, Medicaid and other government health programs but also to lab services paid for by commercial insurers. Luckily, many compliance-conscious labs already vet their private payor arrangements for potential kickback issues, notes Savannah, GA, health attorney Adam Walters. The more serious concern is that EKRA doesn't include the exceptions and safe harbors contained in the AKS and Stark laws to allow leeway for legitimate referral arrangements

that may otherwise raise kickback concerns. Result: There's no way to be sure that arrangements structured to comply with AKS and Stark exceptions and safe harbors will also comply with EKRA.

3 Potentially Problematic Arrangements

Walters says that there are three kinds of commonly used lab arrangements that EKRA calls into particular concern.

1. Variable Compensation Tied to Referrals

Although it doesn't impose a blanket ban on commissions, EKRA does prohibit variable compensation paid by labs that's based on the value or volume of referrals generated, particularly commissions and bonuses to sales and marketers based on the number of patients referred, tests performed and/or payments the lab receives.

2. Leasing of Space in Physicians' Offices

While some states already prohibit this practice, Walters notes that both AKS and Stark create exceptions for labs to make legitimate arrangements to lease space in the offices of referring physicians. But EKRA doesn't include any such exceptions or safe harbors.

3. Accountable Care Organization (ACOs) Participation Agreements

Many labs have taken advantage of current federal waivers to AKS, Stark and the Civil Monetary Penalties law that allow labs to enter into participation agreements with ACOs. However, the federal waiver does not include EKRA, which casts doubt on the legality of existing lab ACO participation arrangements.

Takeaway

Many have suggested that EKRA was rushed into passage without full consideration of these kickback effects. But the corollary to that school of thought is that once the dust settled and the problems became apparent, the government would step in and fix the problem. Relief could come in the form of:

- *Regulatory guidance from the Department of Justice (DOJ) clarifying whether arrangements that meet AKS and/or Stark exceptions or safe harbors also comply with EKRA;*
- *New DOJ implementing regulations setting out EKRA exceptions and safe harbors for particular arrangements, presumably in coordination with current AKS and Stark rules; or*
- *Legislation that eliminates, clarifies or revises the EKRA kickback prohibitions.*

But nearly 16 months after EKRA took effect, none of these things have happened, despite calls for clarification from the American Clinical Laboratory Association (ACLA) and other lab industry groups. We know that the DOJ and Congress are aware of and presumably looking into

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the problems. But so far, nobody has made a move. "The DOJ seems to be waiting for Congress and vice-versa," suggests one expert.

In the meantime, the lab industry has no choice but to assume that EKRA does apply to all existing arrangements, including those structured for AKS or Stark, and review or restructure them accordingly.

Which Labs Does EKRA Cover?

Another unanswered question about EKRA is whether the kickback restrictions apply to all labs or just toxicology labs. The EKRA law's focus is on toxicology, drug treatment centers and sober homes; on the other hand, the language of the statute is so broad that it seems to cover all clinical labs, not just toxicology labs.

Beyond the News: What Does Latest ACA Court Ruling Really Mean?

You've no doubt heard the news about the Dec. 18 federal appeals court ruling striking down part of the Affordable Care Act (ACA) as unconstitutional. But like most people, you're probably wondering what it means. We'll break it down for you.

Bottom Line on Top

The U.S. Court of Appeals for the 5th Circuit court ruling is the latest but far from the last development in the seemingly endless quest of Republicans to cut the constitutional underpinnings out from under the ACA. The challengers got part of what they wanted when the court found that the individual mandate, i.e., the ACA requirement that Americans carry health insurance or pay a tax penalty, is unconstitutional. But they didn't get what they were really hoping for—and even expecting—a ruling finding the entire law unconstitutional, even without the individual mandate.

That was how the lower court came out last December. The individual mandate was an essential part of and couldn't be severed from the ACA, the court reasoned. So, if the mandate was unconstitutional, the whole law was too. The 5th Circuit wasn't prepared to take it that far. Explain your reasoning and analysis more clearly, it instructed the lower court, and we'll decide if you're right.

Practical Impact

In essence, the 5th Circuit ruling decides nothing and prolongs the case for another year or so. That's how long it will probably take for the case to ping-pong back to the appeals court setting the stage for an all but inevitable showdown in the U.S. Supreme Court.

In terms of right now, the three-judge panel's 2-to-1 ruling (2 Republican vs. 1 Democratic appointee) on the mandate has no real immediate practical effect on consumers because Congress had previously decreased the penalty for people who don't have insurance. But the uncertainty over the rest of the ACA will continue to upset the peace of mind of millions of Americans. Ditto for the insurance markets and payors who have much to lose if the entire law is found unconstitutional and the ACA marketplaces are abolished. The other elements of the ACA law at risk of being struck down include:

- Insurance subsidies for people who acquire health plans through ACA marketplaces;
- The expansion of Medicaid in three dozen states;
- The requirement that insurers cover people with pre-existing conditions;
- The ability of young adults to stay on their parents' insurance policies until they turn 26; and
- No-charge preventive care for older Americans on Medicare.

If declared unconstitutional, it's been estimated that 17 million could lose health care coverage, and more than 50 million people with pre-existing medical conditionals could be denied health insurance.

A complete repeal of ACA would also be detrimental to managed care organizations like Anthem, Cigna, Centene that have established themselves in the ACA marketplaces and expanded their footprints there.

ACA also is woven more subtly into many other aspects of the health care system, from payment formulas for hospitals and doctors to experiments intended to nudge health care from a system that pays for the quantity of medical services to one based on the value of care patients receive. Additionally, if ACA is declared unconstitutional, it could undermine the Trump administration's proposals to lower drug prices.

OIG Work Plan: Agency to Focus on Vaccine Adverse Event Reporting

The five new items the OIG added to its Work Plan in December 2019 have no direct impact on labs or lab services, although three of them might have an indirect effect on some labs. Here's the rundown.

1. CDC Cybersecurity Controls Over the Vaccine Adverse Event Reporting System (VAERS)

Issue: Run by the CDC and FDA, VAERS is a national vaccine safety surveillance program that serves as an early warning system to detect possible safety issues with U.S. vaccines by collecting information about

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adverse events (possible side effects or health problems) that occur after vaccination.

OIG Action: The OIG will do an audit of VAERS to determine whether federally required cybersecurity controls are in place.

2. Use of Technology for Emergency Response

Issue: During the 2017 and 2018 California wildfires, some responders used technology-driven tools such as data analytics to locate vulnerable Medicare beneficiaries in a disaster zone and a network of health information exchanges to access patients' electronic medical records and deliver care away from their typical care setting.

OIG Action: The OIG will do a case study addressing two uses of technology during the California wildfires for emergency response, to identify ways that entities can incorporate technology into their own emergency preparedness and response strategies.

3. National Background Check Program for Long-Term-Care Providers: Assessment of State Programs

Issue: The Affordable Care Act (ACA) authorizes CMS to provide grants to states via the National Background Check Program to implement background check programs for prospective employees and providers of long-term-care services. The ACA also requires OIG to evaluate the grant program after its completion.

OIG Action: The OIG will audit the implementation of select Program requirements for conducting background checks completed by states in 2019 to determine the outcomes of the states' programs and whether the checks led to any unintended consequences.

Labs IN COURT

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

Court Refuses to Let M.D./Executives Out of Their Non-Competes

Case: After leaving the national reference lab in which they owned equity and served as executives, a pair of Georgia pathologists wanted to open a competing lab. Standing in their way was the non-compete covenant each pathologist signed when first joining the reference lab. Rather than wait to be sued, the pathologists took the initiative and asked the Delaware court to find the covenants null and void under a Delaware state law banning any contractual provision that purports to prevent a person from practicing medicine for a period of time or within a particular locale once the contract expires. But the court refused and said the covenants were enforceable.

Significance: The point of the law is to protect the physician-patient relationship and practice of medicine. And while the pathologists were physicians, they entered into the contract not as physicians wanting to

treat patients but as executives planning to run a corporate operation. In addition, they practiced in Georgia and the law in question applied only to practice in Delaware [*Bakotic v. Bako Pathology LP, 2019* Del. Super. LEXIS 658].

Fired Pipeline Worker Loses Lawsuit against Drug Testing Lab

Case: A Louisiana pipefitting worker who lost his job at an Exxon petrochemical plant because he tested positive for marijuana sued the testing lab for a laundry list of violations, including failure to carry out the test in accordance with federal Dept. of Transportation (DOT) a Pipeline and Hazardous Materials Safety Administration ("PHMSA") regulations. But the federal court found the claims legally invalid and tossed the suit without a trial.

Significance: The testing lab didn't follow the five-panel drug testing method or apply the high cutoff levels that DOT and PHMSA require for worker drug testing, the court acknowledged. But it didn't have to. The federal rules apply only to testing that an employer must submit to the DOT and PHMSA. And while the plant was subject to those regulations, the testing in this case was done under an internal employment policy. So, the DOT and PHMSA standards didn't apply [*Tilson v. DISA, Inc., 2019* U.S. Dist. LEXIS 216318, 2019 WL 6878867].

Feds Break Up Another Genetic Test Fraud Kickback Scam

Case: The owner of two Pennsylvania genetic testing labs was indicted for allegedly paying kickbacks to generate Medicare referrals for cancer genomic testing (CGx) and pharmacogenetic testing (PGx). The feds claim the owner conspired with business consultants, marketers and a telemedicine operator to acquire thousands of testing samples from elderly patients, along with the corresponding prescriptions they needed to bill Medicare for medically unnecessary CGx and PGx testing.

Significance: The new scheme looks just like the one enforcers busted as part of the Operation Double Helix initiative announced this fall—for the details, see *Lab Compliance Advisor (LCA)*, Oct. 29, 2019—in which marketers used targeted campaigns to induce beneficiaries to submit CGx and PGx specimens by means of cheek swabs sent to their homes or furnished at so called "health fairs" in exchange for percentage-based kickbacks paid by the testing labs.

NYC Lab Shells Out $151K for Accepting Millennium Test Cup Kickbacks

Case: Another month, another hefty sum paid by a lab to settle claims for accepting free point-of -care-test cups from Millennium Health. The most recently announced OIG settlement involves Manhattan-based A.R.E.B.A. - Casriel, Inc. (ACI), which will pay $151,056 for being on the receiving end of those free test cups.

Significance: At least a dozen labs and medical practices have entered

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into similar settlements stemming from the massive Millennium kickback scandal, with settlement amounts ranging from $40.5K to $1.128 million. For a Scorecard listing the details of each settlement, see *Lab Compliance Advisor (LCA)*, Dec. 12, 2019.

Florida Lab, M.D. Settle HDL-Related Kickback Charges for $107.2K

Case: A physician and the medical practice he works for have agreed to pay the OIG $107,260 for allegedly accepting kickbacks from Health Diagnostic Laboratory, Inc. (HDL) Inc. in the form of "process and handling" fees for collection of blood samples, in exchange for referrals.

Significance: The case against HDL and its lab business associate Singulex, Inc. began as a *qui tam* whistleblower lawsuit alleging payments of kickbacks disguised as processing fees of $10 to $17 per test to physicians in exchange for orders of medically unnecessary blood tests; then, by billing Medicare and TRICARE for tests provided under the arrangement, the labs violated the False Claims Act (FCA). In April 2015, the case settled with HDL agreeing to pay $47 million and Singulex $1.5 million. Both labs also entered into Corporate Integrity Agreements with the government.

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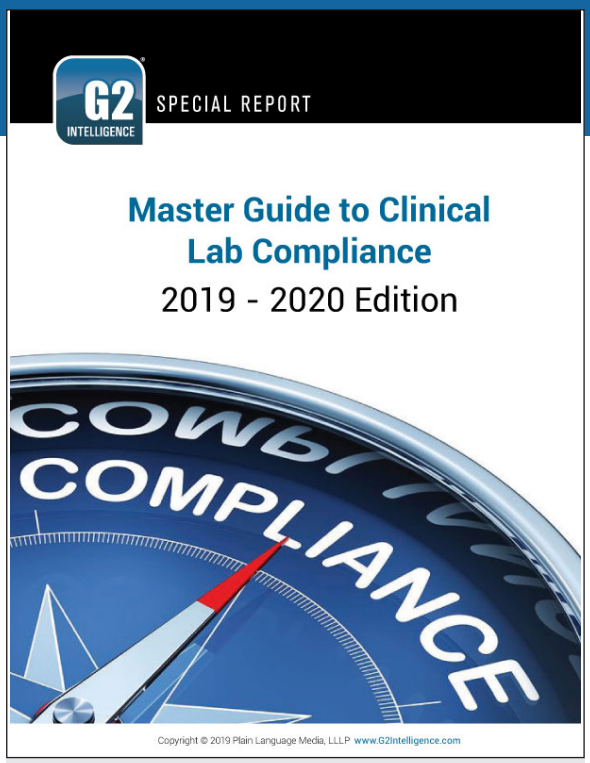

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