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Special Report: Final Rules Offer Real Stark and Kickback Relief but Largely Exclude Labs

With its time apparently running out, the Trump administration completed one of its pet projects by finalizing the kickback reform rules it proposed in October 2019. Issued on Nov. 20, the new final rule (actually a pair of rules, one drafted by CMS and the other the OIG) is designed to modernize the archaic kickback restriction laws in general and facilitate the making of value-based care arrangements in particular. Here's a rundown of the new rules.

Bottom Line on Top—Impact on Labs

Under the proposed rules, the liberalized regime allowing for value-based care arrangements didn't apply to labs. Specifically, the definition of "VBE participant" allowed to participate in so-called value-based enterprises excluded labs. Other excluded providers included pharmaceutical manufacturers, as well as manufacturers, distributors or suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS).

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COVID-19: Labs and Private Payors Clash Over Reimbursement of COVID-19 Testing

Things are getting ugly. The unfortunate convergence of resurgent COVID-19 cases, lingering testing supply bottlenecks and Thanksgiving are once more stretching labs to the breaking point and fraying tempers with labs and insurers trading accusations over the billing of coronavirus tests.

The Capacity Crisis

While Trump administration officials estimate that the U.S. has enough tests to screen between 4 million and 5 million per day in November, those numbers don't account for the

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CMS had no qualms in disclosing its reasons for cutting labs out of the value-based relief package: We don't trust them. Citing its "historical enforcement and oversight experience," the agency expressed concern "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 to create value for patients and payors by improving the coordination and management of patient care." Besides, CMS added, labs aren't on "the front line of care coordination and treatment decisions" the way physicians and hospitals are.

The good news is that the public comments to the proposed rule persuaded CMS to change its mind. Accordingly, the new definition of VBE participant contained in the final rule removes the reference to labs and other specific types of providers. "We find the commenters' assertions that laboratories and DMEPOS suppliers may play a beneficial role in the delivery of value-based health care persuasive," CMS explains. However, it adds, "we will continue to monitor the evolution of the value-based health care delivery and payment system to ensure that the inclusion of all types of providers and suppliers as VBE participants does not create a program integrity risk."

The bad news, though, is that while labs can benefit from the new Stark Law value-based care exceptions, they're still excluded from participating in the parallel anti-kickback safe harbors for value-based care arrangements, as well as other new kickbacks for EHR interoperability, cybersecurity donations and patient incentives.

The Need for Kickback Reform

The principle that providers must make medical decisions purely on the basis of patient needs without self-interest or bribery remains as sound as today as it was when the kickback laws first came into effect three decades ago. The problem is that the prescribed legal restrictions designed to keep referrals untainted haven't evolved to fit the market they're intended to regulate. Stated simply, the kickback laws crafted for a fee-for-services market 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 Trump administration reform initiative culminating in the new final rule 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

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other new issues adversely affected by the kickback laws including cybersecurity, the electronic health record (EHR) and accountable care organizations (ACOs).

The 3 Parts of the Rule

The final rule makes 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 Anti-kickback 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.

The 9 Key Changes

1. New Stark Exceptions for Value-Based Arrangements

The final rule creates three new Stark exceptions allowing for labs and other providers to enter into value-based compensation arrangements with physicians:

1. **Value-based arrangements with full financial risk:** This exception applies when a VBE assumes full financial risk on a prospective basis for the cost of all patient care items/services covered by a payor for the target patient population within 12 months after the arrangement begins.
2. **Value-based arrangements with meaningful downside financial risk:** For this exception to apply, at least 10 percent of the physician's remuneration must be at risk, which can be in the form of paybacks, withholds, incentive bonuses or other payment structures. Under the original proposal, downside risk had to be at least 25 percent of the physician's remuneration.
3. **Other value-based arrangements:** There's also a general exception allowing for any value-based arrangement, regardless of the size or nature of the parties to the arrangement, financial risk undertaken by the VBE or financial risk undertaken by the physician so long as the arrangement meets a detailed list of enumerated requirements.

Impact on Labs: As noted above, labs are not excluded from the new-based exceptions the way they were in the proposed rule. One more important thing to note: To qualify for any of these exceptions, a value-based physician compensation arrangement need only be commercially reasonable. Unlike most other Stark exceptions, the final rule doesn't

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require that such arrangements be set in advance, consistent with fair market and not in any factor the volume or value of a physician's referrals or other business the physician generates for the entity.

2. New AKS Safe Harbors for Value-Based Arrangements

Parallel to the new Stark exceptions, the final rule creates three new AKS safe harbors for value-based arrangements:

1. **Value-based arrangements with full financial risk:** As with the Stark exception, this safe harbor applies when a VBE assumes full financial risk on a prospective basis for the cost of all patient care items/services covered by a payor for the target patient population within 12 months after the arrangement begins, to protect both monetary and in-kind remuneration.
2. **Value-based arrangements with meaningful downside financial risk:** For this safe harbor to apply, a VBE must assume substantial downside financial risk from a payor and a value-based participant must assume a meaningful share of the VBE's total risk to protect both monetary and in-kind remuneration exchanged under value-based arrangements between VBEs and participants.
3. **Care coordination arrangements to improve quality, health outcomes and efficiency:** This safe harbor requires no assumption of downside risk by parties to a value-based arrangement to protect in-kind remuneration exchanged to engage in value-based activities that are directly connected to the coordination and management of care for the target patient population. Recipients must pay at least 15 percent of either the offeror's costs or the fair market value of the remuneration.

Impact on Labs: Even though labs may now be considered "VBE participants," the final rule expressly bars them from participating in the AKS safe harbors for value-based arrangements. Other ineligible entities include: pharmaceutical manufacturers, distributors, and wholesalers, pharmacy benefit managers and DMEPOS suppliers. **Exception:** The rule creates a separate pathway for certain DMEPOS companies to participate in protected care coordination arrangements that involve digital health technology. However, that pathway isn't open to labs.

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. The final rule expands the scope of the Stark EHR exception and establishes 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 percent of the donor's costs.

Impact on Labs: The bad news is that both the expanded Stark exception and new AKS safe harbor excludes labs.

4. New AKS Safe Harbor for Beneficiary Incentives

Another new CMP exception and AKS safe harbor allows for beneficiary incentives under patient engagement and support arrangements designed to improve quality, health outcomes and efficiency.

Impact on Labs: Labs aren't allowed to use the new beneficiary incentives safe harbors. The exclusion list includes the usual suspects but as with the new value-based care safe harbor, leaves a pathway open for DMEPOS companies.

5. New Outcomes-Based Payments Safe Harbor

The final rule expands the current personal services and management contracts safe harbor to payments tied to achieving measurable outcomes that improve patient or population health or appropriately reduce payor costs. The definition of "outcomes-based payment" permitted includes a reward for successfully achieving an outcome measure or a recoupment or reduction in payment for failure to achieve an outcome measure.

Impact on Labs: Once again, the new safe harbor specifically excludes labs.

6. New Definitions Making Stark Exceptions Easier to Use

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

- **Providing "commercially reasonable" compensation:** In the final rule, CMS clarifies that an arrangement is "commercially reasonable," a key criterion for determining if the arrangement qualifies for a Stark exception, if it furthers a legitimate business purpose of the parties and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.
- **In which compensation isn't based on volume or value of referrals:** The final rule clarifies that compensation doesn't 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 final rule redefines 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."

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

Previously, if an arrangement between a physician and a lab (or other provider) didn't meet the requirements of a Stark exception, the physicians had to refrain from making referrals to the lab and the lab refrain from billing Medicare for referred services during a "period of disallowance" after the relationship ends. In the proposed rule, CMS called the period of disallowance rule as "impractical and overly prescriptive" and the final rule eliminates it in favor of a case-by-case assessment depending on the particular relationship involved. CMS also created a special rule that allows parties to "reconcile discrepancies" for compensation arrangements within 90 days of termination of the arrangement.

8. New 90-Day Grace Period for Stark Exceptions

CMS is providing a new period for reconciling non-compliance issues of within 90 calendar days of the expiration or termination of a compensation arrangement, if after the reconciliation, the entire amount of remuneration for items or services is paid as required under the terms and conditions of the arrangement.

9. New Annual $5,000 Stark Exception

The final rule includes a new exception for arrangements in which a lab pays a physician less than $5,000 in a calendar year in exchange for items or services. This 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.

Takeaway

Although the final rule leaves the door open for labs to use the new value-based Stark exceptions, it bars them from the other new exceptions and AKS safe harbors, including those related to EHR, cybersecurity donations and patient engagement. Still, labs will benefit from CMS' general clarification of Stark terminology and expanded grace periods. The other key question is whether all of this is a moot point. The final rule is scheduled to take effect on Jan. 19, 2021, the day before the inauguration of the new president. But while there's always the chance of a new administration's peeling back all or part of a new regulation adopted by its predecessor, particularly when that regulation goes

into effect on the eve of the transition, it's pretty unlikely that the Biden administration will tamper with the final rule, which has the general support of the American Hospital Association and other major medical groups, although several are disappointed that it doesn't go further in reforming the antiquated referral rules.

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 3 Things Labs Must Know

1. The final rule provides significant Stark/AKS relief for value-based care arrangements but largely excludes labs
2. The same is true of relief for EHR interoperability, cybersecurity donations and patient engagement arrangements
3. The good news is that labs will benefit from the general Stark changes, including clarified definitions of crucial terms needed for exceptions

Labs IN COURT

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

Texas Court Nixes Toxicology Labs' ERISA Beneficiary Unpaid Claims Lawsuit against United Healthcare

Case: After United Healthcare denied their claims, plan members assigned their benefits to a pair of toxicology labs who then filed a lawsuit to against United under the federal *Employee Benefits Retirement Security Act* (ERISA) to recover the benefits. In addition to contending that the benefits arrangement was a sham, United moved to have the case dismissed on a procedural ground. And that's just what the Texas federal court decided to.

Significance: ERISA allows beneficiaries sue their health plans for unpaid benefits, provided that they first "exhaust their administrative remedies" before going to court. Although the sides clashed on whether

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the labs actually submitted the claims to United, the labs admitted that they didn't bother to appeal the denials. There were literally thousands of claims and the labs contended that going through the cumbersome six-month appeals process would be futile. But the court disagreed, noting that the "futility" exception to the exhaustion of remedies requirement applies "only in the most exceptional circumstances." Showing that resorting to the appeals process would be a pain in the behind wasn't enough; to prove futility, labs had to show that denial of the appeals would be a certainty.

[*Mission Toxicology, LLC v. Unitedhealthcare Ins. Co.*, 2020 U.S. Dist. LEXIS 205919, 2020 WL 6491662]

Employee Who Tests Positive for Meth Can't Sue Company that Created Workplace Testing Arrangement

Case: After his hair sample workplace drug test came back positive for methamphetamine, a construction worker was assigned to "Inactive" status, meaning that none of the employers in the drug testing consortium arrangement would allow him onto its work sites. The worker contended that the positive test was due to over-the-counter medications and sued the company that ran the testing arrangement for not requiring or requesting testing for d/l isomers. But the Louisiana federal court tossed the case without a trial.

Significance: The worker basically sued the wrong defendant. To be guilty of negligence, a person must owe a duty of care to the plaintiff. However, no such duty between the testing company and the worker in carrying out the testing existed in this case. The testing company merely created and administered the testing program; it didn't collect the samples, perform the tests or perform medical review of positive results. So, the worker didn't have a legally valid claim for negligence against it.

[*Thibodeaux v. DISA Global Sols., Inc.*, 2020 U.S. Dist. LEXIS 204953, 2020 WL 6479540]

Manager Can't Sue Lab for Disability Discrimination After Signing a Severance Release

Case: Things went downhill for a clinical lab manager after he got into a violent confrontation with one of the union stewards representing the phlebotomists he supervised. Two days after the incident, the manager went to the ER for anxiety and was diagnosed with "emotional stress reaction." He then went on disability leave allowing him to work but not at the same facility as the steward. But what was supposed to be just a temporary accommodation dragged on with the employer denying his request for reassignment to a new facility. The manager eventually decided to resign and file a workers' comp claim. But after settling the workers

comp claim and signing a severance agreement and release, the manager had a change of heart and sued the lab for failure to accommodate his disability under the *California Fair Employment and Housing Act* (FEHA). But the state court dismissed the case.

Significance: The release agreement was enforceable, the court concluded, even though it didn't specifically mention the FEHA as among the laws for which the manager released the lab. The manager signed the release voluntarily; and he received "consideration," i.e., something of value, for doing so, namely a $45,000 severance payment.

[*Razon v. S. Cal. Permanente Med. Grp.*, 2020 Cal. App. Unpub. LEXIS 7518, 2020 WL 6737418]

North Carolina Health System Principles Pay $900K to Settle False Billing Charges

Case: The owner and two managers of now defunct Carolina Comprehensive Health Network, PA (CCHN), a group of family medicine practices and pain management services providers in North Carolina, have agreed to fork over $900,000 to settle claims of falsely billing Medicare and Medicaid for medically unnecessary diagnostic tests and procedures. According to the complaint, CCHN submitted false claims for positional nystagmus testing, rotational axis testing, nerve conduction testing and autonomous nervous system testing over a six-month period in 2015.

Significance: This case began as a *qui tam* claim filed by a whistleblower. Although the details are sketchy, the government's decision to intervene in the case was probably a decisive factor in persuading CCHN that it had come time to settle.

Tennessee Operator Fined $9.015 Million for Running Drug Testing Lab After Being Excluded from Medicare

Case: Mr. Dube was excluded from federal healthcare programs in June 2012. But that didn't stop him from establishing American Toxicology Labs (ATL)in Tennessee in May 2013. With Mr. Dube's wife serving as the registered agent, ATL applied to participating in Medicare and Medicaid listing the wife as owner and the couple's home address as its principal office address. even though he had been than a year earlier. Once admitted, ATL performed urine drug screens for opioid treatment facilities generating $8.5 million in false billings to Medicare and Virginia, Kentucky and Tennessee state Medicaid programs, with the excluded Mr. Dube at the helm at all times.

Significance: In addition to running a lab while he was excluded, Mr. Dube received $441,646 in kickback payments for referring Medicare and Medicaid patients to third party providers. In addition to $9,015,046 in fines, restitution and forfeiture, the couple was sentenced to three years of probation, four months of home detention and 400 hours of community service.

Kickbacks: OIG Issues Fraud Alert on Pharmaceutical Company In-Person Speaker Programs

Before the pandemic put the chill on live conference events, it was fairly common for pharmaceutical companies, device makers and diagnostics companies to offer healthcare professionals fees for in-person speaking appearances. Such practices raise red flags under the federal Anti-Kickback Statute (AKS) when those speakers recommend the products of those companies to their patients. So, on Nov. 16, the OIG issued a Special Fraud Alert warning companies about restarting in-person paid healthcare professional speaker programs when COVID-19 restrictions lift.

OIG Skepticism of Speaker Fees Program

Federal government suspicion of paid speaker programs, especially by pharmaceutical companies, is nothing new. For example, Novartis recently agreed to pay $678 million to settle a seven-year-long legal battle with the OIG over allegations of using its speaker programs as a way to disguise bribes to doctors from 2002 to 2011. As part of the deal, Novartis agreed to cut back its future speaker programs.

Salix Pharmaceuticals also ran afoul of the OIG and settled a civil fraud lawsuit settlement for $54 million in 2016, under which it had to admit that it paid doctors as speakers for programs that were mostly social events where little or no time was spent discussing drugs.

So, Why Now?

"We are issuing this Fraud Alert [now]," the OIG explains, to give companies the opportunity to use this time to "assess the need for in-person programs given the risks associated with offering or paying related remuneration."

The OIG specifically called out pharmaceutical industry trade group PhRMA, saying it was "skeptical about the educational value" of programs such as those outlined in PhRMA guidelines for healthcare professionals. The OIG pointed to its own investigations that reveal these professionals often "receive generous compensation to speak at programs offered under circumstances that are not conducive to learning or to speak to audience members who have no legitimate reason to attend."

Of course, the warning is also targeted to the healthcare professionals (HCPs) on the receiving end of these fees, with the Fraud Alert asking HCPs to "consider the risks of soliciting or receiving remuneration related to speaker programs given other available means to gather information relevant to providing appropriate treatment for patients."

The Kickback Red Flags

In the Fraud Alert, OIG states that it's "skeptical about the educational value of such programs." It then cites examples of troublesome practices, including:

- Selecting high-prescribing HCPs as speakers and rewarding them with lucrative speaker deals;
- Conditioning speaker remuneration on sales targets, such as requiring speaker HCPs to write a minimum number of prescriptions;
- Holding speaker programs at entertainment venues or during recreational events or otherwise in a manner not conducive to an educational presentation, such as wineries, sports stadiums, fishing trips, golf clubs, and adult entertainment facilities;
- Holding programs at high-end restaurants where expensive meals and alcohol are served;
- Inviting HCP attendees who previously attended the same program; and
- Inviting friends, significant others, and family members of the HCP who do not have a legitimate business reason to attend the program.

OIG further warns that all parties who participate in speaker programs are subject to scrutiny. This includes pharmaceutical and medical device companies that offer or pay remuneration to HCP speakers and provide free meals to program attendees, as well as HCP speakers who receive honoraria payments and HCP attendees who receive free meals at speaker programs.

Evidence of Intent

The Fraud Alert lists factors it uses to determine whether a speaker's fee arrangement is legitimate or evident of an intent to violate the AKS. The latter include:

- Speaker programs with little or no substantive information actually presented;
- Availability of alcohol;
- Meals exceeding modest value provided to program attendees;
- Programs held at locations that aren't conducive to the exchange of educational information, including restaurants or entertainment or sports venues;
- Sponsoring a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information;
- Significant passage of time with no new medical or scientific information nor a new FDA-approved or cleared indication for the product;
- Repeat attendance by HCPs on the same or substantially the same topics or being an attendee after being a speaker on substantially the same topic;
- Attendees who don't have a legitimate business reason to attend the program;
- Influence of commercial employees over the selection of speakers or attendees based on past or expected revenue the speakers or attendees have or will generate by prescribing or ordering the company's products; and
- HCP speakers paid more than fair market value for the speaking service or compensation takes into account the volume or value of past or potential future business generated by the HCP.

Labs and Private Payors Clash Over Reimbursement of COVID-19 Testing, *From Page 1*

supplies shortages that have bedeviled testing efforts since the public health crisis began. Without the necessary pipettes, reagents and other critical supplies, labs can't process tests in a timely manner or even at all.

Recent FDA authorization of specimen pooling was supposed to ease the pressure. But while it's true that testing a pool of specimens consumes fewer supplies, that theory goes out the window if the pool tests positive and all of the people in the pool must be tested individually to identify the positives. And as cases spike, positives become more frequent and the utility of pooling diminishes.

Medicare Reimbursement Challenges

Adding to the stress are the difficulties labs are facing in getting reimbursed for the COVID-19 tests they do perform. When the public health emergency first began, Medicare paid labs $51 per test for high throughput COVID-19 diagnostic tests. Recognizing that the rate was inadequate, CMS subsequently raised it to $100 per test. However, in October, CMS announced a new payment policy for 2021 under which laboratories will only qualify for the $100 payment rate if:

- They complete the billed test in two calendar days or less; AND
- They complete the majority of high throughput COVID-19 tests in two calendar days or less for **all** of their patients (not just their Medicare patients) in the previous month.

Labs that take longer than two days will receive only $75 per test. In essence, CMS is disguising a reimbursement cut as a reimbursement increase.

Private Payor Reimbursement Challenges

Labs are also facing reimbursement challenges from private payors. The *Families First Coronavirus Response Act* (FFCRA) and *Coronavirus Aid, Relief, and Economic Security Act* (CARES) require insurers to cover COVID-19 tests without seeking copayments or other out-of-pocket costs. However, in June, HHS issued regulatory guidance suggesting that the rule doesn't apply to "testing conducted to screen for general workplace health and safety (such as employee 'return to work' programs), for public surveillance or any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19.

Duelling Accusations

The lab industry contends that health plans and insurers are exploiting this loophole to evade their FFCRA and CARES reimbursement obligations. Health insurance groups have responded by accusing labs of price gouging for COVID-19 tests. The most recent charge comes in the

form of a study from America's Health Insurance Plans (AHIP) based on data from survey of 22 members, representing 76% of commercial enrollment of the trade group's member plans. On average, a COVID-19 test in the commercial market costs $130, and out-of-network tests cost more than $185, the report contends. Its conclusion: "Between 9 percent and 16 percent of out-of-network test claims charged more than $390 (three times the average cost)."

Takeaway

Conflicts between the lab industry and private health insurers over reimbursement of testing is nothing new. But COVID-19 and the relief legislation enacted to address it have opened a new front and raised the stakes. Labs want HHS to close the regulatory guidance loophole and apply the FFCRA and CARES Act coverage mandate to all forms of COVID-19 testing, including the asymptomatic. Meanwhile, AHIP and its allies are calling on Congress to set a "reasonable market-based pricing benchmark" for out-of-network tests to ensure Americans can access COVID-19 tests. And with a new administration taking the reins, the situation remains volatile and highly fluid.

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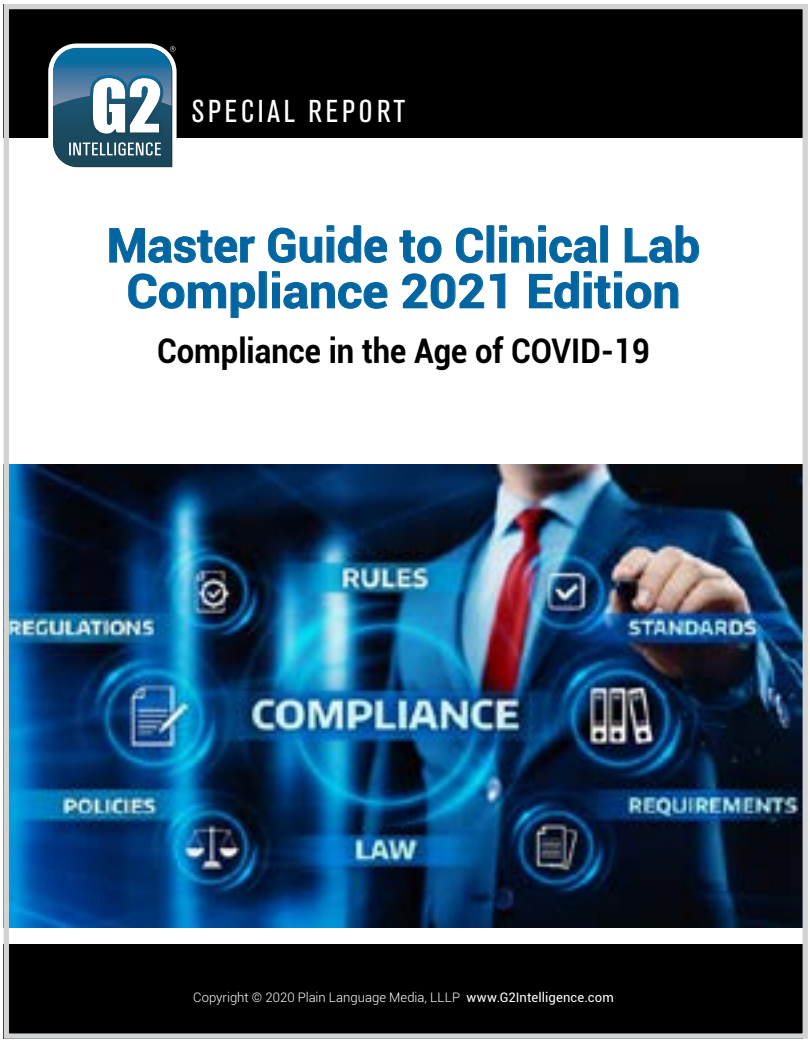
Compliance in the Age of COVID-19



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