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The Year in Labs Regulation: The 9 Biggest Stories of 2020

When 2020 started, COVID-19 was just a news story unfolding on the other side of the globe in China. The novelty of the pathogen meant that there were no tests specifically targeting the virus on the market or in the pipeline. The biggest story of lab regulation and compliance in 2020 was how all of that suddenly and dramatically changed. As the imperative to develop and deliver COVID-19 tests became a national priority of paramount importance, kickback, privacy and other laws were temporarily set aside and new, improvised regulatory regimes sprang into existence. As 2020 comes to a close and the U.S. faces a deadly new surge of cases, here are what we believe were the biggest stories of the year—in a chronological narrative.

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Special Report: Long-Awaited Kickback Relief Rules Leave Labs Out in the Cold

The final rule for value-based care kickback relief that HHS and the OIG published on Nov. 20 is slightly more favorable to labs than the proposed rule published in October 2019. But with a limited exception, the agencies decided to stick with the original plan to exclude labs (along with pharmaceutical manufacturers and DMEPOS suppliers) from the most significant new exceptions and safe harbors, including those covering value-based care. Here's a rundown of the key changes and how they affect labs.

The Government Still Doesn't Trust Labs

CMS was totally open about why it decided to cut labs out of the original value-based relief proposal. Citing its "historical enforcement and oversight experience," the agency expressed

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1. The Feds Temporarily Waive the Kickback and HIPAA Laws

January 30: HHS declares COVID-19 a public health emergency (PHE), thereby activating the HHS Secretary's authority under the *Public Health Service Act* to take broad response measures to deal with coronavirus. One of these powers is to temporarily waive or modify Medicare, Medicaid, State Children's Health Insurance Program and HIPAA requirements under Section 1135 of the *Social Security Act* (SSA). During the next two months, HHS and the OIG issue Section 1135 Blanket Waivers covering the Stark Law and Anti-Kickback Statute, as well as pre-approval requirements and restrictions on telemedicine. **The message:** Right now, delivering COVID-19 diagnosis and treatment is more important than the need to avoid arrangements offering remuneration in exchange for Medicare and other federal referrals.

NIR

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2. The CDC Releases the First COVID-19 Test

February 4: Less than a week after the PHE is declared, the FDA issues the first Emergency Use Authorization (EUA) for a COVID-19 diagnostic test, a real-time reverse transcription polymerase chain reaction panel known as the 2019-nCoV Real-Time RT-PCR Diagnostic Panel developed by the U.S. Centers for Disease Control and Prevention (CDC) using sequencing information made public by Chinese authorities. The test can be used in the U.S. only by CDC-designated labs certified to perform high-complexity testing in accordance with agency protocol.

The plan calls for the CDC to create test kits for distribution to state health departments and public health labs in all 50 states. Things immediately go wrong. The early feedback suggests that a negative result can't be counted on to rule out infection. The CDC acknowledges that it has to remanufacture one of the kit reagents to address the test quality results issues. Precious time is lost.

A "root cause" analysis performed later in the year reveals that a scientist in an infectious disease lab on the CDC's Atlanta campus discovered the assay's high failure rate while putting the test kit through its final paces. Normally, a failure rate of that magnitude would have precluded releasing the test. But the CDC apparently caved to the intense pressure and proceeded to distribute the test. And, so, the federal government testing response gets off to a shaky start.

3. Relief Legislation Ensures Free COVID-19 Testing—Or Does It?

March 18: Congress enacts the *Families First Coronavirus Response Act* (FFCRA) requiring group health plans and health insurers) to provide COVID-19 testing coverage without cost-sharing requirements like deductibles, copayments and coinsurance and without imposing prior authorization and other medical utilization requirements. The

Coronavirus Aid, Relief, and Economic Security Act (CARES) passed less than two weeks later amends FFCRA to cover a broader range of diagnostic items and services that plans and issuers must cover without cost-sharing or prior authorization requirements. CARES also requires plans and issuers to reimburse providers of COVID-19 diagnostic testing an amount equal to its negotiated rate with the provider; if there is no negotiated rate, reimbursement must be at the cash price for such service listed by the provider on a public website.

Once again, things veer off track. In June, HHS issues regulatory guidance suggesting that the free testing mandate 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." By year's end, labs are accusing health plans and insurers of exploiting this loophole to evade their FFCRA and CARES reimbursement obligations, while insurers are accusing labs of price gouging for COVID-19 tests.

4. FDA Approves the First COVID-19 Antigen Test

May 8: The Quidel Sofia 2 SARS Antigen FIA assay becomes the first antigen assay to receive EUA for SARS-CoV-2 use. The product is a point of care test designed for use with the firm's Sofia 2 fluorescent immunoassay analyzer to detect SARS-CoV-2 protein fragments in nasal or nasopharyngeal samples. Its reported sensitivity of 85 percent definitely puts false negatives into play. The agency reportedly cleared the test within 24 hours of receiving Quidel's application. In the coming months, the FDA will grant EUA to nearly a dozen other antigen tests.

5. HHS Hits Labs with Unprecedented COVID-19 Test Data Reporting Duties

June 4: As labs scramble to meet the historic demand for COVID-19 testing, HHS imposes new rules requiring the reporting of not only test results but detailed information about how the test was ordered and performed and for whom, including demographic information about patients. Specifically, labs must complete daily reports for all testing they complete and for each individual they test within 24 hours of knowing or determining the results and send it to state and local public health departments for ultimate transmission to the CDC. And the deadline to comply is Aug. 1.

6. FDA Greenlights Sample Pooling

June 16: Facing continuing shortages of reagents, swabs, PPE and other testing supplies, the FDA issues new guidance to pave the way for sample pooling in which sub-samples extracted from individual samples go into a pool or "batch" that can be tested with a single test. If the entire pool

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returns a positive result, the individual samples are retested to locate the source of the positive; if the batch tests negative, all of the constituent samples are also deemed negative.

On July 18, Quest Diagnostics' SARS-CoV-2 RNA test becomes the first coronavirus test cleared by the FDA for pooled sampling. Over the course of the next few months, more than a dozen other tests receive expanded EUA for use with pooling.

As the year closes, pooling seems to have been a modest success at best. Initially, it provided a measure of needed relief to the overtaxed testing supplies pipeline. However, the new surge of COVID-19 cases that began in November took the wind out of the pooling sails to the extent the technique works best in low-risk populations. Higher case rates mean higher positive rates which, in turn, result in the need to go back and retest all of the individual samples in the pool.

7. Controversy Over FDA Regulation of LDTs

August 19: The biggest story in lab regulation in 2020 involved an issue that has been contentious for decades: FDA authority to regulate laboratory developed tests (LDTs). In March, Congress re-tabled a bill called the *Verifying Accurate Leading-edge IVCT Development Act* (VALID), that would create a risk-based framework for IVCT regulation, with high-risk tests, like novel assays, required to go through premarket review and allowing lower-risk tests could go to market after passing through technological certification.

But the spotlight would shift from the legislative to the regulatory arena where the COVID-19 crisis would bring the LDTs issue to a dramatic and surprising head. When the chips were down, universities, academic centers and commercial labs came through with some of the earliest and most innovative COVID-19 tests to receive EUA. It was a noteworthy accomplishment that seemed to vindicate the lab industry's long-running contention that FDA overregulation of LDTs was thwarting progress and innovation.

Then things got weird. On Aug. 19, HHS announced that the FDA would no longer require premarket review for LDTs but that labs could still seek EUA voluntarily. In addition, the FDA would now have to use the notice and rulemaking process to create new rules and could no longer regulate LDTs via website notices and other informal methods. On Oct. 7, the FDA turned the tables by announcing that it was bowing out of EUA review for any LDTs to "make the best use" of its review resources. And without EUA, labs would no longer be able to rely on the liability protections of the *Public Readiness and Emergency Preparedness Act* (PREP) providing

immunity to producers of tests and other medical products in response to a PHE.

But HHS would have the last laugh. On Nov. 16 the agency ordered the FDA to resume EUA review of COVID-19 LDTs and do it within 14 days or the National Cancer Institute (NCI) would step in to help. And that's where things currently stand with a new president set to take office.

8. The Telemedicine Crackdown

September 30: Like labs, fraudsters were able to pivot their business in response to the pandemic. So did the enforcement community, unveiling "Operation Rubber Stamp," the largest "takedown" in Justice Department history involving 51 federal districts, 345 defendants, including over 100 doctors, nurses and other licensed medical professionals, and $6 billion in false claims. And, while telemedicine providers were the primary target, medical labs got pulled into the dragnet. Many of the defendants in Operation Rubber Stamp are labs and telemedicine operators charged with paying kickbacks to doctors to order medically unnecessary tests for patients with whom they never actually had televisits.

9. New Kickback Rules Exclude Labs from Value-Based Care, Cybersecurity Safe Harbors

November 20: It wasn't all just about COVID-19. One of the biggest stories in 2020 compliance was the finalization of the new Stark and AKS regulations. First the bad news: The rules designed to facilitate value-based care arrangements largely exclude labs, as well as pharmaceutical manufacturers and manufacturers, distributors or suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS). 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," CMS explained. The agency also excluded the same group of its usual suspects from its new cybersecurity donations and beneficiary incentives exceptions and safe harbors.

The good news is that labs weren't cut out from other parts of the final rule, including the clarification of key definitions like "commercially reasonable compensation," the elimination of the Stark "Period of Disallowance" waiting period and the new 90-day grace period for Stark exceptions, among other things.

Enforcement Trends: COVID-19 Distractions Cause 2020 OIG Health Care Fraud Recoveries to Dip to 5-Year Low

Not surprisingly, the COVID-19 pandemic is hampering federal fraud fighting. The recoveries numbers bear this out. Here are the key findings from the OIG's new Semi-Annual Report to Congress summarizing enforcement activities for FY 2020.

2020 OIG Fraud Enforcement by the Numbers

First, some context: After two decades of steady growth, OIG fraud recoveries have been trending downward in recent years. It began in FY 2018, when the recovery figures actually declined for the first time in years. Although recoveries rebounded in FY 2019, the distracting effect of the pandemic has caused the metrics to take another downward turn in FY 2020.

After the decline from $4.13 billion to $3.43 billion between FY's 2017 and 2018, total OIG health care fraud investigative recoveries topped $5 billion in FY 2019, only to turn downward again in 2020 with expected recoveries expected to a total $3.14 billion. The agency also expects to recover another $942.06 million from audits. Additionally, total criminal actions also decreased from 804 to 624, which is lower than even the FY 2018 numbers.

Meanwhile, another metric that began to decline in FY 2018 fell again this year, namely exclusions, which dropped from 2,640 to 2,148. However, civil actions, increased from 695 in FY 2019 to 791 in FY 2020; still, that number is below the 813 civil actions reported in FY 2018. What makes the low FY 2020 number surprising is that it is the first full year total reported since CMS' draconian affiliations exclusion rule took effect See, "The New CMS Medicare Exclusion Rules & How to Comply with It," *National Intelligence Report* (NIR), Oct. 28, 2019.

OIG Enforcement Year Over Year Enforcement Action

Metric	2020	2019	2018
Expected investigative recoveries	$3.14 billion	$5.04 billion	$3.43 billion
Criminal actions	624	809	764
Civil actions	791	695	813
Exclusions of individuals and entities	2,148	2,640	2,712

Labs in the OIG's Crosshairs

As usual, the new OIG Report cites significant recoveries for the year in cases involving labs, including:

- **$41 million against Florida pain clinic:** A Tampa pain clinic and two former executives shelled out $41 million to resolve allegations of falsely billing Medicare, Medicaid, TRICARE and other federal health care programs for medically unnecessary urine drug tests (UDTs). According to the government, the lab had a

practice of automatically ordering both presumptive and definitive UDTs for all patients at every visit, without having a physician make an individualized determination that either test was medically necessary for the patient.

- **Pennsylvania drug and alcohol rehab owner jailed, fined $3.2 million:** The other case the OIG cites involves the co-founder of a rehabilitation organization sentenced to 37 months in prison and ordered to pay $3.07 million in restitution, $110K in forfeitures and a $15,000 fine for his role in several fraud conspiracies, including an elaborate kickback scheme involving thousands of medically unnecessary UDTs referred to Florida-based reference labs.

Takeaway

Even though recovery figures have been trending down over the past three years, the $3.14 billion total for 2020 is shockingly low. What's going on here? Part of the answer is the pandemic. In its Dec. 2 press release, the OIG acknowledged that the COVID-19 pandemic has been its primary focus this year to the detriment of standard enforcement efforts. "Oversight of COVID-19-related issues commanded much of OIG's attention and remains a primary focus," noted ***Christi A. Grimm****, OIG's Principal Deputy Inspector General in the press release. While COVID-19 has spun out its own brand of fraud—witness the Operation Rubber Stamp takedown targeting telemedicine abuses—the year 2020 is a very atypical one for OIG enforcement activity.*

Focus On: OCR Audit Gives Providers Mixed Results for HIPAA Compliance

The *Health Information Technology for Economic and Clinical Health Act* (HITECH Act) requires the HHS Office for Civil Rights (OCR) to periodically audit covered entities and business associates for compliance with HIPAA Privacy, Security and Breach Notification Rules. On Dec. 17, 2020, the OCR announced the findings of its most recent audit covering 166 covered entities and 41 business associates.

The Good News: OCR found that most covered entities:

- Met the timeliness requirements for providing breach notification to individuals; and
- Satisfied the requirement to prominently post their Notice of Privacy Practices on the website they maintain about their customer services or benefits.

The Bad News: The OCR audit also found that most covered entities failed to:

- Provide all of the required content in their Notice of Privacy Practices;
- Provide all of the required content for breach notification to individuals;

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- Properly implement the individual right of access requirements such as timely action within 30 days and charging a reasonable cost-based fee; and
- Implement the HIPAA Security Rule requirements for risk analysis and risk management (this was also the case for most business associates).

HIPAA: HHS Proposes Significant Value-Based Care Changes to HIPAA Privacy Rule

As its days dwindle down, the current administration is mobilizing for one final push to reduce what it perceives to be unnecessarily burdensome regulation, including on the medical privacy front. On Dec. 10, the HHS Office for Civil Rights (OCR) issued a notice of proposed rulemaking (NPRM) to modify the HIPAA and HITECH Act Privacy Rule.

The Proposed Privacy Act Changes

As with the recent kickback regulations, the OCR Privacy Rule initiative is designed to clear the path for value-based health care. Specifically, the NPRM proposes to modify the Privacy Rule to expand the scope of permissible disclosures of protected health information (PHI), i.e., PHI disclosures permitted without the individual's consent, to include disclosures that will promote care coordination and case management communications among individuals and labs, hospitals and other HIPAA covered entities. Key changes proposed:

- Clarifying the definitions of the key terms "electronic health record" and "personal health application";
- Shortening the response time for patient health record requests from 30 days to 15 days (with a 15-day extension under limited circumstances);
- Making it easier patients or their personal representatives to verify their identity when requesting access to their PHI or exercising another Privacy Rule right;
- Creating an exception to the "minimum necessary" standard for individual level care coordination and case management uses and disclosures;
- Clarifying the minimum necessary standard with respect to care coordination and case management activities;
- Removing obsolete parts of the Notice of Privacy Practices (NPP) requirements;
- Amending the permissible fee structure for responding to patient health record requests and requires covered entities to post estimated fees on their website for access and for disclosures with a patient's authorization;

- Making it easier for family and caregiver to be involved in the care of individuals experiencing emergencies or health crises; and
- Modifying provisions on individuals' rights of access to PHI.

Takeaway

The deadline to comment on the NPRM is March 11, 60 days after its publication in the Federal Register. *If it's finalized—and that's a big "if" considering that a new administration will be in control—the final rule would take effect 60 days after it's published. Labs and other covered entities and their business associates would have until the "compliance date" to establish and implement policies and practices to achieve compliance with any new or modified standards. Among other things, you'd then have to:*

- *Update your information privacy policies and procedures and train lab employees on the changes;*
- *Revise your Notice of Privacy Practices; and*
- *Renegotiate business associate agreements to comply with the new requirements.*

National Intelligence Report *(NIR) will keep an eye on things and explain how to do each of the above when and if it appears that the changes are really going to happen.*

Scam Alert: OIG Warns Medicare Beneficiaries Not to Fall for COVID-19 Scams

Pharma companies, diagnostics manufacturers, labs and other parts of the healthcare industry have done a commendable job in pivoting in response to the current public health industry. Sadly, scammers have been just as successful. On Nov. 23, the OIG issued a new alert warning the public about fraud schemes related to COVID-19.

The Face of COVID-19 Fraud

The OIG says that scammers are taking advantage of the coronavirus pandemic to collect personal medical information of Medicare and Medicaid beneficiaries to commit identity theft and fraudulently bill federal health care programs. And if Medicare or Medicaid denies the claim for an unapproved test billed, the beneficiary could also end up being responsible for the cost.

OIG describes the different methods fraudsters have been using to target beneficiaries, including telemarketing calls, text messages, social media platforms, and door-to-door visits. The alert cites examples of actual schemes, including:

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- After hacking social media accounts, fraudsters are sending direct messages to beneficiaries posing as a friend or government employee notifying beneficiaries of their eligibility for government grants, and urging them to call a phone number to collect the funds. Upon calling, the beneficiary is asked to pay a "processing fee" (using bank account information, gift cards, bitcoin) to receive the grant money.
- Fraudsters are offering COVID-19 tests to beneficiaries in exchange for personal information, including their Medicare and Medicaid information.
- Scammers posing as medical labs are targeting residents of retirement communities with offers of COVID-19 tests so they can draw blood and bill federal health care programs for medically unnecessary services.
- Some scammers have been offering people $200 Medicare prescription cards when no such cards currently exist.

8 Ways Consumers Can Protect Themselves

The OIG alert lists recommendations for consumers to avoid being scammed:

1. Being suspicious of unsolicited requests for Medicare or Medicaid numbers or personal/medical/financial information or offering COVID-19 tests or supplies;
2. Understanding that Medicare doesn't call beneficiaries to offer COVID-19 related products, services, or benefit review.
3. Not responding to or opening hyperlinks in text messages about COVID-19 from unknown individuals.
4. Not responding to offers or advertisements for COVID-19 testing or treatments on social media sites.
5. When making an appointment for a COVID-19 test online, confirming that the location is an actual testing site.
6. Being mindful of the fact that only physicians or other trusted healthcare providers should assess medical condition and approve requests for COVID-19 testing.
7. Not providing personal or financial information to anyone claiming to offer HHS grants related to COVID-19.
8. Being on the lookout for scammers posing as COVID-19 contact tracers. Legitimate contact tracers will never ask for Medicare numbers, financial information, or attempt to set up a COVID-19 test and collect payment information for the test, the alert notes.

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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.

But after hearing the public comments, CMS relented. But just a little bit. The agency revised the definition of value-based enterprise (VBE) participant entitled to benefit from the new Stark exceptions to include—or, to be more precise, so as not to expressly exclude—labs and DMEPOS suppliers. However, the OIG was less generous and decided to stick to its original decision to exclude labs from the new parallel *Anti-Kickback Statute* (AKS) safe harbors for value-based care arrangements, EHR interoperability, cybersecurity donations and patient incentives.

The 9 Key Changes

When you boil down the 1,000+ pages of the final rule, there are nine key changes that most labs need to be aware of:

1. New Stark Exceptions for Value-Based Arrangements: Labs Included

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

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.

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.

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-

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based physician compensation arrangement need only be commercially reasonable. Unlike most other Stark exceptions, the final rule doesn't 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: Labs Excluded

The final rule creates three new AKS safe harbors for value-based arrangements that mirror the new Stark exceptions, including for arrangements with full financial risk, meaningful downside financial risk and care coordination arrangements to improve quality, health outcomes and efficiency regardless of whether downside risk is assumed.

Impact on Labs: Being "VBE participants" enables labs to participate in the Stark exceptions but not the AKS safe harbors. **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: Labs Excluded

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 exclude labs.

4. New AKS Safe Harbor for Beneficiary Incentives: Labs Excluded

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: Labs Excluded

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: Labs Included

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."

7. Elimination of Stark "Period of Disallowance" Waiting Period: Labs Included

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.

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8. New 90-Day Grace Period for Stark Exceptions: Labs Included

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: Labs Included

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:

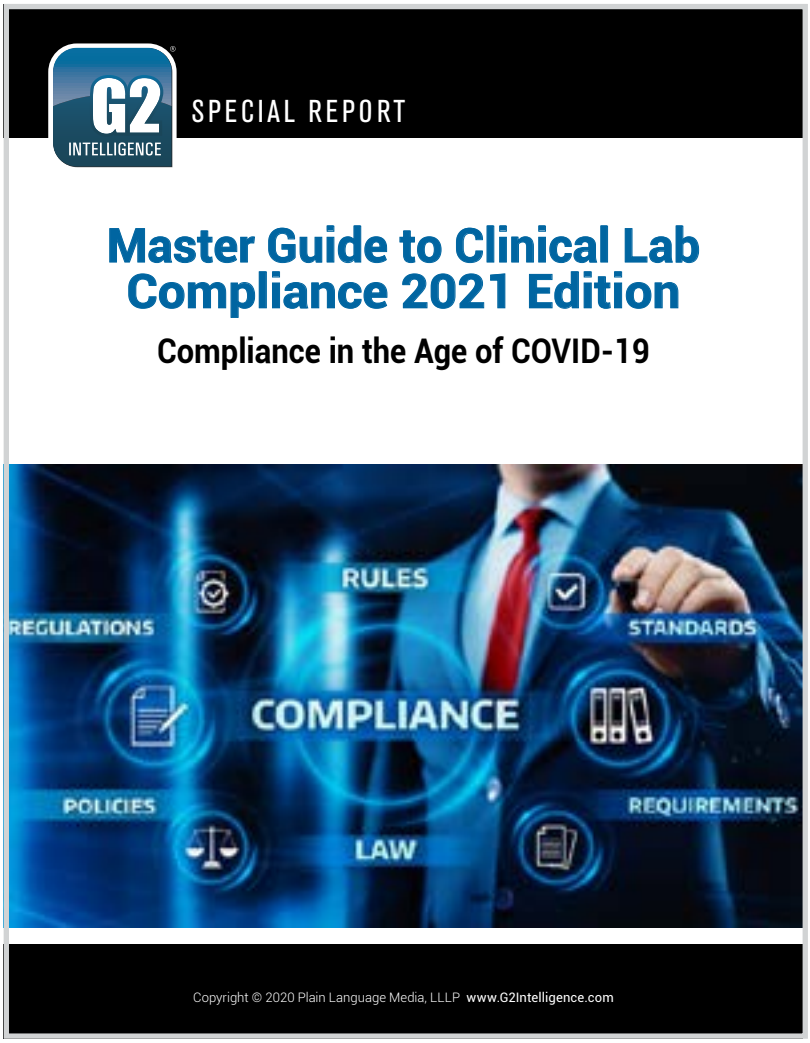
- The physician actually provides the services or items the compensation covers;
- The arrangement furthers a legitimate business purpose;
- The terms and conditions are similar to like arrangements;
- The remuneration isn't based on the value or volume of referrals; and
- The remuneration reflects fair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

Takeaway

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.

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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