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Special Report: Long Awaited Kickback Relief Rules Keep Labs in the Cold

They're finally here! After years of talking about adapting the decades-old kickback laws to modern medical market conditions, CMS and OIG proposed new rules (the Proposal) on Oct. 9, 2019. Whether it was worth the wait remains to be seen. But one thing is clear about the new proposal: It's very long—386 pages to be exact. And in case you don't have the time or desire to hack your way through the whole document, or the resources to hire an attorney to do it for you, just scan this overview of the key changes and what lab managers need to know about them.

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Compliance Perspectives: California Case Illustrates Lab's Liability Risks for "Causing" MDs to Submit False Claims

False Claims Act (FCA), 101: Knowingly submitting a false claim to Medicare or another federally funded health care program is a violation. But what's lesser known is that your lab can also be liable for an FCA violation without actually submitting a claim. How? Answer: By "causing" a third party to submit a false claim. violates the False Claims Act (FCA). A new California federal court ruling offers new insight into this significant but often overlooked "cause to submit" rule.

What Happened

The case, *United States of America v. Carolina Liquid Chemistries*, was a whistleblower suit brought by a former CEO and a former corporate director of a urine drug testing (UDT) equipment manufacturer. Their contention: Specifically, the equipment the UDT company manufactured was capable of performing only "qualitative" drug testing producing a yes/no result for certain classes of drugs; but the company marketed the product as being capable of performing quantitative chromatography or mass spectrometry test that can detect and measure the quantity of specific drugs. In addition to being more complex, "quantitative" testing is reimbursed at a higher rate than qualitative testing. for specific drugs and their quantities even

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BOTTOM LINE ON TOP

Although CMS and OIG are offering real kickback relief for value-based care, EHR, cybersecurity and other modern health care arrangements, they're also proposing to exclude labs from the new, liberalized rules.

LCA

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Why New Kickback Rules Are So Desperately Needed

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

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

The 3 Parts of the Proposal

The Proposal suggests revisions to three different kickback laws:

- The Stark Law (Stark), which bans physicians from referring patients to entities with which they or immediate family members have a financial relationship;
- The 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.

Labs Excluded from the New Value-Based Arrangement Rules

First, the bad news. The proposed changes allowing for value-based (VB) care arrangements don't apply to labs. Adding insult to injury is CMS' explanation for excluding labs: "On the basis of our historical enforcement

and oversight experience, we are concerned that [some labs], which are heavily dependent upon practitioner referrals, might misuse the proposed safe harbors primarily as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care." Besides, CMS adds, labs aren't on "the front line of care coordination and treatment decisions" the way physicians and hospitals are.

THE OTHER EXCLUDED PROVIDERS

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

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

The 8 Key Changes

1. New Stark Exceptions for VB Arrangements

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

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

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2. New AKS Safe Harbors for VB Arrangements

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

1. Coordination arrangements to improve quality, health outcomes and efficiency;
2. VB arrangements with substantial downside financial risk; and
3. VB arrangements with full financial risk.

3. New Exception/Safe Harbor for Cybersecurity Donations

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

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

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

4. New AKS Safe Harbor for Patient Engagement Arrangements

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

5. New Definitions Making Stark Exceptions Easier to Use

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

- Providing "commercially reasonable" compensation: CMS is proposing two possible definitions of "commercially reasonable": (i)"the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements"; or (ii) "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type

and size and a reasonable physician of similar scope and specialty";

- In which compensation isn't based on volume or value of referrals: The Proposal suggests that compensation would not meet that criterion if:
  - It uses a mathematical formula that includes referrals or other business generated as a variable; and
  - The compensation amount correlates with the number or value of a physician's referrals to an entity;
- In which compensation reflects fair market value: The Proposal would redefine this critical term to match the definition that applies to the exception for equipment or property rentals, i.e., the "value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction."

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

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

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

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

8. New Annual $3,500 Stark Exception

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

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

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Takeaway: The Need for Labs to Engage

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

The good news is that there's still time to right these wrongs. It can't be overemphasized that the Proposal is just that, a proposal. The agencies are quite candid throughout the Proposal, freely admitting that they don't trust labs and calling on stakeholders to weigh in and try to change their mind before the comment period ends on Dec. 31, 2019. Bottom Line: The lab industry has a unique and crucial opportunity to dispel old prejudices and make its case for being allowed into the VB care and cybersecurity arrangements that will define medicine in the decades to come.

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though it was designed to perform only simple "qualitative" drug testing.

Of course, while it may be illegal under other laws, false marketing of equipment doesn't necessarily make a company liable for committing an FCA violation since the company doesn't actually bill for the services the equipment is used for. And that's where the "causing" language of the FCA came into play. The whistleblowers claimed the manufacturer "caused" its physician office to submit false claims by instructing them to "upcode" claims by using CPT codes for more complex and higher-paying UDT tests than were actually performed.

What the Court Ruled

In addition to denying the accusations, the company argued that the whistleblowers didn't have a valid FCA claim for "causing to submit" because they couldn't identify *which claims* the company allegedly caused to be submitted to Medicare and Medicaid. The U.S. District Court for the Northern District of California agreed and granted the company's motion to toss the whistleblowers' claims without a trial. In so doing, the court made two crucial rulings:

1. No Need to Point to Specific Claims

First, the company said that the whistleblowers didn't have a valid claim because they couldn't identify *which claims* it allegedly caused the physicians' offices to bill. But the court rejected that argument. While some federal courts in other Circuits may take a different position, the Ninth Circuit (where California is located) doesn't require whistleblowers to "identify representative examples of false claims to support every allegation." Instead, all a whistleblower has to do is "allege particular details of a scheme to submit false claims paired with reliable indicia that

lead to a strong inference that claims were actually submitted." This is particularly true, the court added, where the claim is based on a "causing to submit" theory.

2. Whistleblowers Do Have to Explain How Scheme Worked

But the company had more success with its second argument, namely, that the whistleblowers didn't specify exactly what it did to cause physicians' offices to submit the false claims. Showing why the marketing claims were false and that upcoding took place, assuming the whistleblowers could prove those allegations, wouldn't be enough. To prove an FCA violation, the whistleblowers had to show how the marketing scam actually worked—the "who, what, when, where and how of the alleged fraud"—and how it resulted in causing false claims to be billed. But the complaint didn't list any of these crucial details, the court found.

The good news for the whistleblowers is that it wasn't a final defeat since the court said they could amend the complaint and fill in the missing particulars.

Takeaway: Liability Risks for Causing Third Parties to Submit False Claims

Recognize that the false representations you make in your marketing materials and activities can expose you to risk of FCA liability if downstream clients rely on those misrepresentations to submit false claims. For lab managers, the significance of the Carolina Liquid Chemistries case is in illustrating the parameters of "causing to submit" liability in whistleblower lawsuit.

The lesson is that at least in most federal Circuits, whistleblowers don't have to trace back allegations of false marketing to specific Medicare or Medicaid claims submitted by downstream clients or customers. As long as the whistleblowers can show that a fraudulent scheme took place and how it worked, courts will infer that the target of the scam submitted false claims as a result. The reason the whistleblowers in Carolina Liquid Chemistries lost is that they showed the marketing claims were false but not how the scam worked.

Enforcement Trends: New Takedown Is Evidence that Genetic Testing Has Become an Enforcement Priority

It's a pretty good sign that fraudulent billing of genetic lab testing has become a priority for federal fraud enforcers when it gets its very own "takedown." Known as Operation Double Helix, the initiative was a joint HHS, DOJ and FBI crackdown carried out in five federal districts against 35 defendants associated with genetic testing labs (CGx) and telemedicine companies, including doctors, CFOs and CEOs that allegedly "capitalized on the fears of elderly Americans to induce them to sign up for unnecessary or non-existent cancer screening tests," according to one of the U.S. Attorneys involved. Here's a rundown of what lab managers need to know.

The Next Generation of Lab Kickbacks

The alleged kickback scheme follows a familiar pattern of paying doctors for referrals of Medicare patients for lab tests. But it also feels like a more modern version of abuse to the extent it brings together things that largely didn't exist in the 20th century, including:

- DNA cancer screening;
- Telemedicine; and
- Identity theft.

How the Scam Worked

In the first phase of the scam, "recruiters" contacted Medicare beneficiaries either online, on the phone or face-to-face at health fairs, senior centers, low-income housing areas or religious institutions like churches and synagogues and made the following pitch: We'll provide you free genetic testing to determine your cancer risks and how well you'd respond to certain drugs; all we need from you is a swab from your cheek, your Medicare information and a copy of your driver's license.

A decade ago, this pitch would have drawn a blank stare. But in this era of consumer awareness of the benefits of genetic testing, it was not only familiar but also highly appealing. "It never crossed my mind that there was anything wrong with this," noted one of the beneficiaries who took the bait. Recruiters also used scare tactics to get beneficiaries to enlist. "You don't want to end up suffering from some horrible disease, do you," they threatened.

The next phase of the scam: Get the beneficiaries' doctor to order the tests in return for a cut of the Medicare payment. If the doctor refused, the recruiters would go to plan B: having one of their assembled cadre of doctors write a prescription for the tests, even those doctors didn't know or examine the beneficiary.

In stage three, CGx labs in on the scam performed the prescribed tests and billed them to Medicare to the tune of $1.7 billion in total. When Medicare

paid the bill, typically in the $10,000 to $18,000 range, the testing lab, ordering doctor and telemarketing firm that recruited the beneficiary split the money.

In most of the cases, the test results were useless to the beneficiary's doctor; in many cases, those results weren't provided at all. But what beneficiaries did get was a big fat charge to their Medicare account that ate into their deductible and reduced their financial coverage for genetic tests that they may actually need in the future. The other harm, of course, was in turning over their sensitive personal information to scammers.

Takeaway: Operation Double Helix is the latest and most obvious indication that genetic testing fraud has become a central focus of federal enforcement. On June 3, 2019, the OIG issued a genetic testing fraud alert warning beneficiaries of exactly the kinds of scams perpetrated in Double Helix. See National Intelligence Report (NIR), *July 15, 2019. There has also been a series of individual and non-coordinated enforcement actions against labs for genetic testing fraud. (To find out more about the crackdown and how to protect your lab, see G2 Blog.)*

Work Plan: OIG Targets Medicare Part B Urine Drug Testing

Falsely billing Medicare Part B for urine drug testing has loomed large on the OIG's radar even before the opioid crackdown began. Last February, for example, the OIG issued a report claiming that CMS made over $66.3 million in improper payments for tests done to validate specimen samples, a form of testing not deemed medically necessary under Medicare coverage criteria. See Lab Compliance Advisor (LCA), April 10, 2018. And now the agency has made review of urine drug testing part of its Work Plan. According to the OIG, in 2028, urine drug and other lab testing had an improper payment rate of nearly 30%. The overpayment rate for definitive drug testing for 22 or more drug classes was 71.7%, it contends. Accordingly, the OIG says it will review urine drug test services provided to Medicare beneficiaries to determine whether they met all the rules and

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coverage criteria.

Among the other five new Work Plan items for October, two may indirectly affect at least some lab providers and companies.

1. Hospice Inpatient and Aggregate Cap Calculations

Issue: There are two annual caps on Medicare payments to hospice providers. The inpatient cap limits the number of payable days of inpatient care to 20% of a hospice's total Medicare patient care days and requires providers to refund any payment amounts above the cap within five months. The aggregate cap limits the total aggregate payments that an individual hospice can receive in a cap year based on an annual per-beneficiary cap amount and the number of beneficiaries served. As with the inpatient cap, providers must repay amounts exceeding the aggregate cap within five months.

OIG Action: The OIG will review Medicare administrative contractors (MACs) oversight of the cap process and determine whether hospices are remitting excess payments in full and in time.

2. FDA Postmarket Surveillance of Medical Devices

Issue: The FDA is getting more of the information it needs to assess medical device safety and effectiveness comes from the postmarket setting. That makes it more important than ever to ensure that the FDA's postmarket safety surveillance system can effectively identify and act on safety signals.

OIG Action: The OIG will assess and describe how the FDA's established passive postmarket surveillance system identifies, tracks and responds to safety concerns, and assess FDA's response to those concerns. It will also describe how elements of the agency's newer surveillance system initiatives, like the Unique Device Identification system, are being integrated into the passive postmarket surveillance system, and how FDA plans to integrate these initiatives into its in-development active postmarket surveillance system, aka, the National Evaluation System for health Technology.

Labs IN COURT

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

ACLA Goes for Knockout Punch in PAMA Lawsuit

Case: Having survived a first-round setback, the American Clinical Laboratory Association (ACLA) went back on the offensive asking a federal court to strike down CMS' scheme for implementing PAMA's market-based prices for lab tests as "unreasonable" and contrary to the intent and terms of the statute. The agency's decision to exclude hospital labs from data collection resulted in artificially low prices that don't reflect true market rates, the ACLA contends. Consequently, some labs "face a serious

threat of being forced out of business, others are being forced to scale back essential services, and patients are being deprived of the services they need."

Significance: The court challenge is, in some ways, just a sideshow in the lab industry's campaign for PAMA pricing relief. If ACLA prevails on the summary judgment motion, CMS would probably appeal to the federal circuit court, just the way ACLA did last year when the roles were reversed and CMS won on summary judgment. A decisive litigation outcome would probably require years, and perhaps a Supreme Court ruling. Chances are, the issue will be decided way before then via negotiation and compromise. And if CMS doesn't relent on the regulatory front, there's also the possibility that Congress will intervene by enacting new pricing legislation. The real significance of the court case is in how it affects leverage. Thus, winning on summary judgment would put the ACLA and lab industry in a much stronger bargaining position. (For more on the PAMA court challenge, see Lab Compliance Advisor (LCA), Sept. 10, 2019.)

New Jersey Lab Pays Over $300K to Settle Specimen Supply Kickback Claims

Case: The latest lab to get into trouble for offering free specimen collection supplies to ordering physicians is Histopathology Services LLC d/b/a Pathline Emerge. After self-disclosing the conduct, the New Jersey lab agreed to pay $310.978 to settle kickback claims.

Significance: Free test cups and other specimen collection supplies seem pretty minor and routine and certainly not the kind of "remuneration" that triggers the kickback law. But the OIG takes a much different view. The most notorious example is the Millennium case involving free point-of-care test cups. In October 2016, Millennium agreed to a $256 million settlement, which is still a record high for a case involving health care fraud by a lab.

Feds Take Down Florida Substance Abuse Clinic Principles for Drug Test Fraud

Case: A trio of individuals associated with a Miami substance abuse facility were charged with taking part in a scheme to bill private insurers for tests that weren't medically necessary or, in some cases, ever provided. As has become the norm in these cases, the defendants also face charges of money laundering.

Significance: The Miami bust is part of the larger coordinated healthcare fraud "takedown" that was announced in September targeting 67 individuals across four federal districts who are allegedly responsible for $160 million in fraudulent billing.

Hospital Stops Paying Lab After It Fails to Provide Medical Necessity Audit Records

What Happened: Blue Cross Blue Shield (BCBS) initiated a billing audit of an Alabama hospital after noticing its average urine drug tests had

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spiked from 30 to 1,100 per month. The hospital asked its lab provider to furnish the physician orders and other records BCBS auditors needed to verify the tests were medically necessary but the lab didn't provide them. As a result, BCBS denied the hospitals' claims. In turn, the hospital withheld the $245,000 it still owed the lab under their lab services contract. The lab sued the hospital for breach of contract.

Ruling: The lab moved for summary judgement, i.e., a ruling in its favor without a trial but the Alabama federal court refused. The hospital violated the contract by not paying the lab; but the lab also violated the contract by not providing the records the hospital needed to give the auditors. Was the lab's violation a "material breach" justifying the hospital's refusal to meet its own contractual obligation to pay? A trial would be necessary to answer that question, the court concluded [Riverboat Group v. Creek, 2019 U.S. Dist. LEXIS 179753].