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For Clinical and AP Laboratories and Pathology Practices

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INSIDE THIS ISSUE

Compliance Perspectives: Feds Using Medicare Laws to Prosecute Non-Medicare Arrangements

Myth: Risk of federal prosecution for health fraud and abuse applies only when you deal with Medicare, TRICARE or other federal health programs.
Truth: While that used to be true, the times they are a-changin'. In recent years, DOJ enforcers have broadened their targeting to include not just state Medicaid but also private commercial healthcare activity. And they're finding new laws and new theories to do it. Result: Most if not all of your lab's business relationships and ventures are becoming subject to federal scrutiny.

The Traditional Boundaries

Historically, federal health care enforcement concentrated on federal health programs and states focused on state programs. Of course, there's more to compliance than healthcare fraud and abuse. Accordingly, in conducting their business, labs are also exposed to risks of liability under other federal and state laws, such as antitrust, OSHA, consumer fraud, medical malpractice, etc.

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Brief Your CEO: Explain How New DOJ Guidance Can Get Your Lab Out of FCA Hot Water

New guidance from the DOJ sheds light on a crucial matter that many high-ranking lab executives are forced to confront: whether to "play ball" with the federal government when internal misconduct is discovered, in this case, False Claim Act (FCA) violations. The guidance lays out a veritable roadmap that labs can follow when they're under investigation to obtain the best result possible. So, it's essential that you bring it to the attention of your C-Suite.

Setting the Stage

Start your briefing by establishing the big picture context. Explain that the FCA, which makes it illegal for contractors to defraud federal government programs like Medicare, is the

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But while the existence of prosecution risk hasn't changed, the nature of it has. Today, federal health enforcers are willing and able to deploy their vast array of resources to pursue wrongdoing in realms of activity it traditionally left to the states and other federal regulatory agencies. In effect, when you violate a state law or federal commercial law, you may also be committing a violation under federal health fraud laws.

EKRA & the Opioid Crackdown

One of the things driving this trend is the enactment of new legislation making extending federal Anti-Kickback Statute (AKS) and Stark Law liability beyond Medicare to Medicaid and non-government commercial healthcare activity. Exhibit A: In October 2018, a series of new federal laws designed to crack down on illegal opioid distribution and use took effect. One of those laws, the so called *Eliminating Kickbacks in Recovery Act of 2018* (EKRA), creates criminal penalties for "patient brokering," an arrangement in which a third party enrolls an addicted patient into a private health insurance plan and then arranges for that patient to enter a treatment facility or sober home in exchange for a kickback payment. **Significance:** Under previous law, a brokering arrangement could be prosecuted as an AKS or Stark violation only if it involved a patient in Medicare, Medicaid or other government health program; it can't be used to prosecute brokering arrangements involving patients with commercial or private-pay insurance. But unlike AKS and Stark, EKRA is an "all-payor" statute that applies not just to government health programs but also lab services paid for by commercial insurers.

What EKRA Says

EKRA makes it a federal crime, carrying a fine of up to $200,000 and/or imprisonment for up to 10 years, to knowingly and willfully:

- Solicit or receive any remuneration for referring a patient to a recovery home, clinical treatment facility or lab; or
- Pay or offer any remuneration either to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility or lab.

Federal Prosecution for Commercial Health Fraud

Parallel to EKRA is the increase in DOJ prosecutions against health providers for fraud outside the context of federally funded health programs. This trend has been most apparent in Texas where there have been several recent cases of federal prosecution for commercial fraud committed by providers.

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The Forest Park Case

The most significant of these cases involves the now-defunct Forest Park Medical Center operating as an out-of-network physician-owned surgical hospital in the Dallas area. Federal prosecutors alleged that Forest Park paid over $40 million in kickbacks disguised as consulting fees for marketing services to entities owned or controlled by physicians in exchange for private patient referrals in violation of the AKS. The more surgeries doctors referred, the more they earned.

If it had been just about the AKS, this would have been pretty routine prosecution. But what made the case novel is that the DOJ also charged the defendants with violating a much lesser known law called the *Travel Act* which makes it a federal offense to carry on interstate commerce for the purposes of carrying on unlawful activity under another statute—

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in this case, the Texas commercial bribery statute (Texas Penal Code §32.43). Specifically, the DOJ alleged that individuals associated with Forest Park bribed physicians with cash, gifts, discounted leases and other remuneration to direct patients with commercial insurance to its own facilities and steer patients with lower-reimbursing federal programs like Medicare and Medicaid to others. It also allegedly engaged in routine waivers of copayments and deductibles.

Ten defendants pled guilty. On April 10, 2019, the federal jury rendered its verdict on the nine defendants who risked a trial: seven were convicted, one was acquitted and the other got at least a temporary reprieve due to a deadlocked jury.

Takeaway: You don't need us to warn you not to commit commercial fraud. But what we can tell you that you may not already know is that you're not safe from federal prosecution just because your arrangement doesn't involve Medicare, Medicaid or another federal program. The DOJ is getting aggressive in rooting out fraud and waste in the commercial healthcare market, and finding new laws and novel theories to do so. Result: This is probably a good time to vet your private payor arrangements to ensure they comply with FCA, AKS, Stark and other federal fraud and abuse laws.

OIG Monthly Work Plan Review: May 2019

Of the three new items in this month's OIG Work Plan items, one may have implications for some labs.

Access to Medication-Assisted Treatment at Health Centers
Issue: Medication-assisted treatment (MAT) is a significant component of the treatment protocols for opioid use disorder and plays a large role in combating the opioid epidemic in the United States. Congress has taken sustained action to support MAT services through broadened prescribing authorities, increased federal funding, and enhanced insurance protections. However, a treatment gap continues to exist where less than 1% of the people in the United States who need treatment for substance use disorder receive it.

OIG Action: OIG will examine access to MAT through health centers funded by the Health Resources and Services Administration (HRSA). Health centers are key entities to expand access to MAT because they provide both primary care and behavioral healthcare services and accept patients regardless of their ability to pay. Additionally, in recent years, HRSA has awarded grant funding specifically to expand access to substance use disorder treatment at health center sites. OIG will examine how many health centers provide MAT services, what types of services they provide (e.g., specific medications, behavioral health services such as

counseling), how many of their providers are waivered to prescribe MAT drugs, and how many patients they are treating with MAT. It will also examine the factors that may facilitate or hinder the provision of MAT in health centers.

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principal law used by the DOJ to go after labs and other health providers and that it provides for treble penalties for violations.

Although the government has extremely potent and investigative resources, it also has a policy of encouraging providers to police themselves and come clean when they discover problems rather than wait for investigators to find the problems themselves. The chief incentive the DOJ uses is reducing the penalties and damages to labs and other entities or individuals that voluntarily:

Self-disclose misconduct that may trigger FCA liability and administrative remedies;

- Cooperate with FCA investigations and settlements in other ways; and/or
- Take adequate and effective remedial measures to correct problems.

Conclude the intro by noting that DOJ attorneys have wide discretion in deciding how to apply these principles in cases where the party under investigation cooperates.

Introduce the New Guidance

Next, explain that the point of the new DOJ's new Justice Manual guidance is to set out clear criteria for DOJ attorneys to use in providing credit for voluntary disclosure, cooperation and remediation.

General Principles

The idea of credits is to reward behavior based on its value to the government in resolving point. So, the starting point for breaking down the guidance are the four general factors it instructs DOJ attorneys to consider in determining the value of voluntary disclosure and additional forms of cooperation, including:

- The timeliness and voluntariness of the assistance;
- The truthfulness, completeness, and reliability of any information or testimony provided;
- The nature and extent of the assistance; and
- The significance and usefulness of the cooperation to the government.

Make it clear to your execs that *no credit* should is awarded for taking steps that the person under investigation is otherwise legally required to do, such as replying to subpoenas or investigative demands.

BRIEF YOUR CEO, *from page 5*

1. Voluntary Disclosure

After summarizing the general principles, go through each of the three forms of voluntary assistance one at a time starting with voluntary disclosure. Note that labs that make proactive, timely, and voluntary self-disclosure to DOJ about FCA misconduct can expect to receive credit leading to a more favorable resolution of the case. Even if the lab is already being investigated, they can earn credits by shedding light on the matters under investigation or voluntarily self-disclosing additional misconduct going beyond the scope of the current investigation.

2. Other Forms of Cooperation

Next, talk about other forms of cooperation starting with an explanation of which activities count under the category. The guidance lists 10 examples:

- Identifying individuals involved in or responsible for the misconduct;
- Disclosing relevant facts and identifying opportunities for the government to obtain evidence relevant to the investigation that the government doesn't already know about;
- Preserving, collecting and disclosing relevant documents and information beyond existing business practices or legal requirements;
- Identifying individuals who are aware of relevant information or conduct, including an entity's operations, policies, and procedures;
- Making the lab's officers and employees available for meetings, interviews, examinations or depositions;
- Disclosing facts relevant to the investigation gathered during the lab's independent investigation, including attribution of facts to specific sources, timely updates on the internal investigation and rolling disclosures of relevant information;
- Providing facts relevant to potential misconduct by third parties;
- Providing information "in native format" and facilitating review and evaluation of that information;
- Admitting liability or accepting responsibility for the wrongdoing or relevant conduct; and
- Assisting in the determination or recovery of the losses caused by the lab's misconduct.

3. Remedial Measures

The third type of conduct to cover in your briefing are actions to remedy FCA violations. Explain that remedial actions may include:

Demonstrating an analysis of the cause of the underlying conduct and, where appropriate, remediation to address that cause;

- Implementing or improving compliance programs to ensure the misconduct

or similar problem doesn't recur;

- Disciplining or replacing those responsible for the misconduct, as well as those with supervisory authority over the area where the misconduct occurred; and
- Taking additional steps demonstrating recognition of the seriousness of the misconduct, acceptance of responsibility for it, and the implementation of measures to reduce the risk of repetition of such misconduct, including measures to identify future risks.

Credit for Disclosure, Cooperation & Remediation

Having explained how credit is earned, the next part of the guidance addresses how it's applied. Explain that there's no concrete formula and that credit earned, if any, will vary based on the unique facts of the case. One thing that *is* hard and fast: The maximum credit can't exceed an amount that would result in the government receiving less than full compensation for the losses caused by the FCA misconduct, factoring in legal costs and whistleblower awards.

If credit is earned, the DOJ may not only cut the penalty or damages for the FCA matter, but also take steps to help the lab (or individual) with its other legal issues, such as:

- Notifying a relevant agency about the lab's disclosure, other cooperation, or remediation, so that the agency in its discretion may consider such factors in evaluating its administrative options, such as suspension, debarment, exclusion, or civil monetary penalty decisions;
- Publicly acknowledging the lab's or individual's disclosure, other cooperation, or remediation; and
- Assisting the lab in resolving *qui tam* litigation with a whistleblower.

Summary

Finish your briefing by explaining the significance of the guidance. The clear message is that labs and other providers have much to gain by self-disclosing, cooperating and taking remedial steps. The first and most direct reward is the very real prospect of reduced penalties and damages for the FCA violations involved. However, the guidance also makes it clear that earning credits can also gain labs government help in resolving other legal problems as well as damage to the lab's reputation, which could translate into huge savings in legal and public relations fees.

The other key thing your execs need to understand is that just doing what the law requires isn't enough. The DOJ is asking for more than responding to subpoenas and standing aside to allow investigators do their jobs. To earn credits, labs must self-police in a literal sense by exercising the same determination to identify and resolve FCA problems that an investigator or whistleblower would.

Case of the Month: U.S. Supreme Court Gives Whistleblowers Four More Years to Sue

Just as the tide seemed to be turning against whistleblower lawsuits (see "New DOJ Policy Targeting Whistleblowers with Weak Cases May Make Life Easier for Labs," (*Lab Compliance Advisor*, March 4, 2019), the U.S. Supreme Court has effectively extended the statute of limitations for bringing *qui tam* lawsuits under the *False Claims Act* (FCA) from six to 10 years. Here's a look at the recent case and what it portends for labs and health providers.

What the FCA Says

Rule: Under Section 3731(b)(1) of the FCA, whistleblowers have six years from the date of the alleged violation to file a *qui tam* lawsuit. However, Section 3731(b)(2) creates an alternative statute of limitations of three years from the date an "official of the United States" knew or should have known the facts of the alleged fraud up to 10 years after the violation. In theory, the alternative limitation period could serve as an extender that gives a whistleblower three extra years to bring claims that first came to light over six years after they were committed. But until now, the belief has been that the alternative limitations period doesn't generally apply to whistleblower lawsuits.

The Question

The Section 3731(b)(2) alternative limitation applies when the government intervenes in the suit since, by definition, the government can't make that decision unless it has notice of the alleged fraud. But does the Section 3731(b)(2) limitation of up to 10 years also apply when the government doesn't intervene?

Three different federal circuits have tackled that question and each has given a different answer. So, when the issue came up again, the Supreme Court decided to accept the case, called *Cochise Consultancy v. U.S. ex rel. Hunt*, to resolve the conflict.

The *Cochise* Case

Although the case applies directly to health care, *Cochise* actually involved a qui tam lawsuit against defense contractors. The whistleblower, Mr. Hunt, filed the case in 2013 for fraud allegedly committed in 2006. Although Mr. Hunt had missed the six-year Section 3731(b)(1) window, he claimed that he first reported the fraud to the government in 2010. And even though the government had declined to intervene, he argued that having brought the matter to the DOJ's attention less than three years earlier, he still had time to sue under the Section 3731(b)(2) knowledge of an "official of the U.S." limitation.

The lower court rejected the argument. But the 11th Circuit reversed, ruling that the three-year extension isn't tied to government intervention but knowledge of the alleged violation. The U.S. Supreme Court then resolved the issue by unanimously affirming the 11th Circuit's ruling. *Both*

FCA statutes of limitations apply to civil whistleblower lawsuits, said the Court, regardless of whether the government decides to intervene in the case.

Takeaway: Unless and until Congress amends the FCA, whistleblowers essentially have 10 rather than six years to bring a qui tam *lawsuits against your lab. Some whistleblowers may seek to take advantage of this extra time granted by Cochise to dredge up old cases that are now back in play—assuming, of course, the alleged events happened within the past 10 years. Of greater concern are the risks going forward, namely, that whistleblowers will use the up to four years extra to hang onto their claims to increase the amount of fraud and thus potential damages they can recover.*

Labs IN COURT

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

West Virginia Medicaid Recovers $17 Million for $8.5 Million Opioid Scam

Case: A subsidiary of Acadia Healthcare Co. has agreed to pay $17 million to settle charges of falsely billing West Virginia Medicaid for opioid-related tests. The DOJ claims that over a six-year period, Acadia-owned drug addiction centers across the state billed Medicaid directly for moderately to highly complex blood and urine analyses actually performed in a San Diego reference lab, charging Medicaid substantially higher rates than the centers paid the California lab. By the time it was uncovered, the scheme had cost West Virginia $2.8 million and the federal government $6.3 million.

Significance: The double penalty, i.e., $17 million settlement for an $8.5 million loss, is no accident. First, Acadia is a high-profile, publicly traded company with over $760 million in reported 2019 Q1 revenues. The other aggravating factor is that this case took place in West Virginia, a relatively poor state whose relatively high opioid addiction rate has placed a significant burden on the state's Medicaid program. Acadia subsidiary CRC Health runs outpatient facilities in several towns across West Virginia.

Authors of Genetic Testing Conspiracy Preying on Seniors Sent to Jail

Case: It's off to jail for the ringleaders of a conspiracy to bill Medicare for $430K worth of genetic tests. The leading defendant, a lab sales rep, posed as a representative of The Good Samaritans of America to get access to senior citizens living in low-income housing communities and used fear tactics to persuade them to submit to genetic testing suggesting that they'd get heart attacks, stroke and cancer if they weren't tested. The defendant recruited providers on Craigslist and paid them thousands of dollars per month to sign requisition forms ordering tests for patients they never actually saw. He and his co-conspirators in turn received over $100K in commission payments from the labs which they divided among themselves.

Significance: The sentence was stiff: 50 months in prison, three years of supervised release, $434,963 in restitution and forfeiture of another $66,844. Two weeks later, another of the co-conspirators was sentenced to 19 months and a third to 13 months in prison.

New York Breaks Up $28 Million Medicaid Diagnostics Mill

Case: One of the biggest Medicaid diagnostics fraud schemes in recent memory has resulted in multiple convictions, including two doctors and two corporate presidents. According to New York prosecutors, the key defendants, including the owner of a pair of diagnostic clinics, the head of medical management firm and a complicit physician—used street recruiters to offer patients cash payments of between $20 to $50 to go to

the defendant's clinics for a battery of unnecessary tests. By the time it was done, the massive medical mill had billed $28 million worth of tests to Medicaid and Medicaid MCOs, proceeds the defendants divvied up among themselves under a secret revenue sharing plan.

Significance: This scheme, which required undercover agents and a stream of warrants to discover, wasn't just sordid but elaborate. In an attempt to give the mill the face of legitimacy, an unlicensed individual was hired to pose as a physician to order tests in the name of physicians involved in the scheme. Even the test technicians were involved as the tests ordered for a particular patient were based on which technician happened to be on duty that day.

Florida Providers Shell Out $733K+ for Self-Disclosed Lab Test Kickbacks

Case: The OIG entered into separate settlement agreements with the three providers involved in a self-disclosed kickback arrangement. Although the details weren't disclosed, Orlando Foot & Ankle Clinic (OFAC) apparently received some form of remuneration to refer patients to Mid-Florida Pathology, LLC (MFP) and Laboratory Services for Central Florida, LLC (LSCF) for lab testing. The settlement scorecard:

- OFAC: $418,256;
- MFP and LSCF: $314,497.

Significance: The unusual thing about this case is not that it was self-disclosed but that all three parties involved in the transactions participated in the self-disclosure. It's unclear whether the parties acted in concert or whether somebody was "ratted out." It's also unclear whether the strategy paid off. Although the fines do appear to be on the low side, it's difficult to make a judgment without knowing the volume and dollar value of OFAC referrals it generated.

Pennsylvania M.D. Used Addiction Clinics as Front for Opioid Scheme

Case: A 57-year-old doctor pleaded guilty to running an elaborate opioid distribution and insurance fraud scheme out of the Liberation Way addiction treatment center for whom he served as medical director and sole physician. Federal prosecutors claimed the doctor signed blank test order forms, prescribed drugs and created medical treatment plans for patients without actually seeing them. "He never even stepped foot into one of the three treatment centers that billed in his name," according to the DOJ press release.

Significance: Remember the name Liberation Way because you'll probably be hearing a lot more of it in the months to come. Last March, criminal charges were filed against nine businesses and 11 individuals in connection with the scheme. All of the elements are there—exploitation of

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opioid addicts, massive overbillings and kickbacks involving thousands of medically unnecessary urine tests which were sent to Florida-based labs for analysis. So, stay tuned. . .

Texas Health System Fined $431K for Falsely Billing Genetic Tests

Case: The feds contend that between 2016 and 2018, Decatur Hospital Authority (d/b/a Wise Health System) sent samples from surgical patients to Tennessee labs for medically unnecessary genetic tests. Rather than risk a trial, Decatur has agreed to settle the claims for $431,182.

Significance: This case is the most recent example of how prosecutors and whistleblowers have begun applying traditional lab fraud laws, e.g., false billing and kickbacks, to newfangled genetic testing. One of the biggest cases was the 2018 $11.4 million settlement with Natera over alleged false billing of the Panorama sequencing-based prenatal screening test. (For more details, see *Lab Compliance Advisor (LCA)*, March 26, 2018.)