G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

# LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

April 2019

## INSIDE THIS ISSUE



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## Compliance Perspectives: How to Spot & Avoid Kickback Risks under New EKRA Law

A new law passed to deal with the opioid epidemic has significant ramifications for labs including but not limited to those involved in drug addiction and recovery programs. Specifically, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) impacts labs' financial relationships with individuals or legal entities hired to generate business for the lab. Accordingly, it's imperative to review all your current marketing compensation arrangements and make necessary modifications to ensure compliance with new EKRA rules. Here's how:

### What EKRA Says

Nobody denies that fraudulent business practices by drug addiction centers and toxicology labs have contributed to opioid drug use and distribution and that tough new rules are warranted.

In October 2018, Congress passed the Support for Patients and Communities Act setting out measures to deal with the opioid crisis. EKRA is the part of the legislation that addresses drug addiction center fraud and abuse. Specifically, EKRA imposes penalties of up to $200K and 10 years in prison for paying remuneration to induce or reward referrals to labs, clinical treatment facilities and recovery

*Continued on page 2*

## Brief Your CEO: Notify Your Lab Execs of Upcoming Stark Law Changes

One of the best ways to score points with your lab's executives is to warn them about legal changes before they happen and while there's still time to prepare. And now you have an opportunity to do just that. Making this opportunity even sweeter is that the law involved is one of the biggest nemeses of any lab, namely, the Stark Law, and that the upcoming changes are likely to be very favorable. Here's what to cover in your briefing.

### Explain the Stark Law

Set the stage by reminding the execs that the Stark Law is designed to prevent physician self-referrals and ensure that physicians order services based on patient needs rather than the physician's own

*Continued on page 8*

COMPLIANCE PERSPECTIVES, *from page 1*

homes, including knowingly and willfully:

- Soliciting or receiving any remuneration in return for referring a patient to a lab, clinical treatment facility, or recovery home; or
- Paying or offering any remuneration to induce a referral of an individual, or in exchange for an individual using the services of a lab, clinical treatment facility, or recovery home.

What's so bad about that, you might be thinking. After all, aren't these practices already banned by the Anti-Kickback Statute (AKS) and Stark Law (Stark)?

## The 3 Problems with EKRA

Kickback bans are nothing new. But the problem with EKRA, which took effect when it was passed in October, is that it's so much broader than the AKS and Stark. Lab industry concerns:

- EKRA is an "all-payor" statute, i.e., it applies not just to Medicare, Medicaid and other government health programs the way AKS and Stark do but to lab services paid for by commercial insurers; and
- The EKRA covers ALL labs not just toxicology labs; and
- Among the things EKRA bans are common lab business arrangements that are currently permissible under both the Stark Law (Stark) and the Anti-Kickback Statute (AKS).

## Beware Business Arrangements that Comply with AKS/Stark but Not EKRA

Perhaps the biggest practical concern for labs is that existing marketing arrangements that comply with Stark and the AKS may now be technically illegal because they don't comply with EKRA. Common arrangements that may now be problematic:

**Marketing Bonuses/Incentives:** One of the arrangements made suspect by EKRA are incentive and performance bonuses paid by labs to marketing personnel. Because these payments are pegged to the value or volume of referrals, they're also problematic under Stark and the AKS. However, both laws currently provide safe harbors (like the AKS employee-compensation and personal services and management contracts safe harbors) and exceptions for bona fide marketing employees receiving productivity bonuses, notes attorney **Andrew Wachler** of Wachler & Associates PC. But unlike Stark and the AKS, EKRA has no safe harbor for such arrangements. Result: Marketing incentives that comply with Stark and the AKS may violate EKRA, Wachler warns. This includes existing incentives that labs carefully vetted when they first put them into place.

**Marketing Commissions:** Also suspect under EKRA are independent contractor marketing arrangements paid on a commission based on volume or value of lab services billed or collected. Many labs hire independent contractor marketers on a commission basis even though there are no applicable AKS safe harbors or Stark exceptions. However, these arrangements are much more problematic under EKRA.

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**Doctor Offices with In-Office Labs:** Stark allows for the creation of doctor's offices with in-office labs provided that certain requirements are met. But EKRA includes no such exception or safe harbor. Although EKRA's language isn't completely clear, Wachler suggests that the government could argue that doctors are receiving remuneration from lab work for patient referral in violation of EKRA. "Certainly, we do not believe this was the intention of EKRA, and we would not recommend that doctors modify their in-office lab arrangements," he adds.

## Practical Impact: 3 Steps to Take

Bottom Line: Labs need to gear up for EKRA now.

**Step 1: Be Aware of EKRA:** The first thing to do is recognize that EKRA exists and that, technically, you may be in violation of it. It's unclear how EKRA will be enforced. The fact that it took effect immediately after it passed with no grace period suggests that labs may get at least a temporary respite, experts suggest. (See the box below for more on possible EKRA relief.) Still, you can't assume relief is coming.

**Step 2: Review Your Marketing Agreements:** You need to revisit the compensation provisions of your marketing agreements with employees and independent contractors to ensure they comply. This is true even if you've already vetted these arrangements under AKS and/or Stark requirements.

**Step 3: Make Any Needed Modifications:** If you identify problems, you'll need to modify your agreements. In doing so, keep in mind that while EKRA doesn't include any safe harbors, it does provide exceptions allowing for payments by a lab (or other employer) to an employee or independent contractor as long the payment isn't based on:

- The number of individuals referred to a particular lab, recovery home or clinical treatment facility;
- The number of tests or procedures performed; or
- The amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular lab, recovery home or clinical treatment facility.

### EKRA Relief May Be on the Way

Meanwhile, there's still a chance that EKRA may turn out to be a false alarm. "There is a great deal of lobbying going on to both amend EKRA and to get regulatory clarification," notes attorney **Charles C. Dunham**, IV of Epstein Becker Green. For HHS has yet to release a proposed regulation or enforcement guidance. When it does, it may include (or call for public comments soliciting ideas for) provisions to limit the extent and reach of EKRA. Example: The EKRA statute doesn't specifically define or cross-reference the terms "laboratory" and "laboratory services." Accordingly, Dunham suggests that HHS could impose narrow definitions tying the terms to providers of substance abuse and addiction services to provide some relief to the wider lab industry.

# OIG Monthly Work Plan Review: March 2019

This month, there were 16 new Work Plan items. Three of these may have implications for some labs as detailed below.

## 1. Medicare Market Shares of Mail Order Diabetes Test Strips

**Issue:** The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) requires HHS-OIG to determine the market shares of diabetes test strips (DTS) supplied via mail order to ensure that Competitive Bidding Program contract bids cover at least 50 percent, by volume, of the DTS types provided to Medicare beneficiaries. This is known as the "50-percent rule."

**OIG Action:** The Bipartisan Budget Act of 2018 amended the 50-percent rule by requiring the use of data from mail order and non-mail order Medicare markets. OIG has been conducting Medicare market share evaluations for DTS provided via mail order since 2010.

## 2. Medicaid Fraud Control Units Fiscal Year 2018 Annual Report

**Issue:** OIG provides guidance to the Medicaid Fraud Control Units (MFCUs), assesses MFCUs' compliance with Federal regulations and policy, and evaluates MFCUs' adherence to published performance standards.

**OIG Action:** This annual report will analyze the statistical information that was reported by the MFCUs for 2018, describing in the aggregate the outcomes of MFCU criminal and civil cases. It will also identify trends in MFCU case results.

## 3. Potential Duplication of NIH Research Grant Funding

**Issue:** The National Institutes of Health (NIH) has 27 Institutes and Centers that manage research initiatives that include awarding grant funding. The Departments of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (Public Law No. 115-245) and its Accompanying Report directed that OIG examine the NIH's oversight of its grantees' compliance with NIH policies, including NIH efforts to ensure the integrity of its grant application and selection processes.

**OIG Action:** OIG plans to review NIH's efforts to ensure the integrity of its grant application and selection process by testing NIH's internal controls for identifying and addressing potentially duplicative grant funding and overlap within its 27 Institutes and Centers. The objective of the review will be to determine whether NIH's internal controls were effective in ensuring that grantees did not receive duplicative NIH grant funding.

# PAMAgeddon: GAO Official Acknowledges Flaws in Lab Price Report as a Powerful Senator Enters the Scene

In November 2018, the U.S. Government Accountability Office (GAO) issued a controversial report suggesting that the new PAMA system will result in billions of dollars worth of Medicare *over*payments for future tests. And now it turns out that the GAO report may have been seriously flawed. That conclusion comes not from the lab industry but the actual report author.

## The GAO Report Brouhaha

To assess the future financial impact of CMS' implementation of new PAMA lab payment rates, the GAO analyzed 2016 Medicare claims data. The conclusion: By 2020, Medicare costs could increase by as much as $10.3 billion due to the unbundling of certain lab panel tests. The GAO also suggests that labs are receiving "excess payments" by no longer charging Medicare reduced rates for bundled tests.

Of course, this conclusion flies directly in the face of what the lab industry and other critics have been saying about PAMA. The lab industry lost no time in criticizing the report, contending that the GAO's findings on unbundling and excess payments are based entirely on a fundamental misunderstanding of how labs bill and are reimbursed for panel testing. Rather than acknowledge the standard practices of billing Medicare for panel tests based on CPT codes currently carried out by the vast majority of labs across the country, the GAO "concocted a hypothetical scenario that suggests labs are unbundling certain panel tests and receiving larger reimbursements for individual tests," according to an American Clinical Lab Association (ACLA) press release.

"It's clear that the GAO overlooked standard industry practices and instead concocted hypothetical scenarios to inform its recommendations and conclusions," the press release continues. "In the process, the report neglects the dangers that CMS' year-over-year cuts pose to the clinical laboratory industry and the patients they serve."

## The GAO's Admission

While not necessarily agreeing with the ACLA's conclusion, the GAO has admitted that at least part of its contentions with regard to methodology are true. The GAO's findings are *not* reflective of current industry practice, but based on a hypothetical scenario, acknowledged **James Cosgrove**, GAO health care director and author of the report, during a recent interview.

However, Cosgrove wasn't backing down and continued to defend the report's findings. "We weren't analyzing what labs are or aren't doing," Cosgrove said. "We were analyzing what the exposure to Medicare would be."

## The Grassley Factor

Meanwhile, one of the country's most powerful lawmakers has waded into the controversy. Elected to the Senate in 1980, Senator **Charles Grassley**

PAMAgeddon, *from page 5*

(R-Iowa) has become a fierce advocate for lower health care prices and a thorn in the side of the drug companies. And this January, he became one other thing: Chairman of the powerful Senate Finance Committee.

Senator Grassley read the GAO report; and he apparently believed it. And now he's determined to find out what CMS intends to do to fix the "overspending" on lab tests problem. In a recent letter, he poses a series of specific questions.

### Senator Grassley's 6 Questions to CMS on Supposed PAMA Lab Overpayments

1. What steps have been taken to ensure that all labs which are expected to report data to HHS actually do so?
2. Does HHS agree with the GAO recommendation that CMS phase in payment-rate reductions based on actual rather than maximum rates? If so, what steps have been taken to amend relevant HHS rule(s) and implement the GAO recommendation?
3. Does HHS believe it has the authority to create CPT codes for panel tests where they don't currently exist, or take other steps to ensure the completion of a bundled payment while remaining compliant with the provisions of PAMA and other relevant federal laws? If so, why has HHS paid individual rather than bundled rates for these panel tests?
4. Did CMS make a systems edit to its claims processing system that prevented CMS from detecting whether individually billed tests should have been bundled? If so, why?
5. What's the status of efforts to detect panel tests where CPT codes do exist but haven't been correctly billed by labs? When does CMS believe it will be able to effectively detect and correct the billing problems?
6. Did CMS know how many labs billed individual tests and received a higher reimbursement rate when they should have billed as a panel code during the time the claims processing system was unable to detect when a panel CPT code was appropriate? Is CMS able to perform an audit to determine that number and the cost in excess reimbursement?

While Grassley's letter does ask some important questions, it also overlooks lab industry concerns. Indeed, some of the questions flat-out ignore key points. For example, Grassley asks whether CMS can create new CPT codes for panel tests and enforce existing panel test codes so it can continue to make bundled payments while remaining compliant with PAMA. He also asks whether CMS plans to amend a rule so it can base pricing reductions on average instead of maximum Medicare payment rates.

*Takeaway: Grassley's questions seem to reflect an indifference to lab industry concerns. Yet, his intervention may prove a blessing in disguise. While his agenda is to cut medical prices, Grassley is also known as a dogged investigator who's fair, intelligent and determined to unearth the truth, precisely the qualities that many in industry believe have been missing in PAMA pricing implementation.*

# Traps to Avoid: Giving Ex-Lab Employees Access to PHI

Your lab staff understands the imperative of safeguarding personal health information (PHI) and wouldn't let strangers roam about the facilities freely. But it's easy for them to lower their guard when a former employee comes back to the lab, e.g., to pick up a final paycheck or just make a social call. Ex-employees are a common and virulent privacy threat, even when they leave on good terms. Many a lab has learned this truth the hard way after PHI was compromised by a former employee returning to the scene.

## Problem: Ex-Employees Pose Greater Privacy Risks

While ex-employees may look like a familiar face rather than a data security threat, they pose serious privacy risks precisely because they are so familiar. Their familiarity literally opens doors that are firmly closed to strangers. Moreover, their familiarity with your lab and its physical facilities, computers and IT systems empowers them to quickly and easily access the PHI you keep. Just allowing the person to walk to an ex-colleague's work station without escort may be ample opportunity to compromise thousands of records.

## Solution: Treat Ex-Employees Like Strangers

Chances are, your lab policies already provide for excluding access of all ex-employees to PHI, including those that had full access when they were employed by your lab. But it's also important to remind reception and other public-facing staff of this policy lest they get lulled into a false sense of security or just feel flat embarrassed having to keep an old colleague away from PHI like some kind of common outsider. Here's a Model Memo you can adapt to deliver that vitally important message.

## TOOL Model HIPAA Privacy Reminder to Reception and Other Lab Staff

From time to time, former employees may visit XYZ Laboratories facilities to pick up personal belongings, visit staff members for professional or social purposes. While XYZ Laboratories is generally welcoming of visits from old friends and colleagues, staff are reminded that once individuals leave employment with us, they are no longer entitled to access protected health information (PHI).

As difficult as it may feel personally, XYZ Laboratory staff members, particularly receptionists and others that face the public, are reminded that **for purposes of HIPAA and privacy compliance, ex-employees are and must be treated like any other visitors to XYZ Laboratories facilities.**

In accordance with this Policy, ex-employees must not be permitted to enter any area of the facility where PHI is stored, used or accessible unless the required precautions required for data security under the XYZ Laboratories Visitors' Policy are fully implemented.

If an ex-employee refuses to cooperate, please notify your supervisor or XYZ Laboratories security immediately. Failure to adhere to this policy that result in compromising data security and making XYZ Laboratories PHI accessible to ex-employees will result in discipline up to and including termination, regardless of whether the ex-employee commits or attempts to commit any actual breaches.

Brief Your CEO: Notify Your Lab Execs of Upcoming Stark Law Changes, *From Page 1*

financial interests. Suggest that while this remains a valid objective, the Stark Law provides a Jurassic solution to a 21st century problem. That's because the Stark Law was designed in and for the fee-for-service context of 1989, a world that no longer exists.

## The Winds of Change

Continue by noting that these problems are universally recognized and that there's been talk of revising the Stark Law for years. Up to now, talk of Stark reform has been just that—talk.

But it appears that the latest efforts aren't just another false alarm. Note that just last year, CMS solicited feedback on how the law should be changed for modern times and received more than 300 comments from hospitals and providers. Among the suggestions:

- Don't punish providers for inadvertent violations such as missing a signature or using an incorrect date; and
- Create an exception for providers in value-based arrangements.

Even more encouraging were the remarks of CMS Administrator **Seema Verma** during her recent speech at the Federation of American Hospitals conference indicating that by the end of the year, the Stark Law will get the biggest makeover it's ever had since its inception back in 1989.

Today, medical dollars are spent on outcomes, not individual services. "In a system where we're transitioning and trying to pay for value, where the provider is ideally taking on some risk for outcomes and cost overruns, we don't have nearly as much of a need to interfere with who's getting paid for what service," Verma noted in her speech.

## Changes to Expect

Let your execs know that Ms. Verma said that CMS is currently working on regulations designed to ensure Stark's workability for value-based and other modern conditions without compromising its effectiveness in deterring Medicare referral abuses and protecting program integrity. She suggested that the changes will be unveiled later this year and are expected to include:

- Clarification of the regulatory definitions of volume or value, commercial reasonableness and fair market value;
- New rules addressing lack of signature, incorrect dates and other forms of technical noncompliance; and
- New provisions allowing for arrangements addressing cyber-security, EHR and other digital challenges.

Wrap the briefing by explaining that you'll be tracking events and will immediately relay any new developments. And, while you don't need to say this to the execs, keep in mind that when the changes are published, we'll let you know what they say, what they mean and what to do to comply with them.

# Enforcement Trends: CMS Orders Medicare Contractors to Go After Labs that Received Specimen Validity Test Payments

Reflecting the wider opioid crackdown, CMS is targeting labs that perform urine drug testing for potential billing abuses. The hottest initiative: Labs that bill specimen validity testing (SVT) in combination with urine drug tests. A February 2018 OIG report claims Medicare made $66.3 million worth of improper payments for such tests and calls on CMS to get that money back. The agency has heeded the recommendation and unleashed the Medicare contractor dogs. Meanwhile, labs are stepping up and voluntarily self-disclosing that they received such payments. Here's a rundown of the situation.

## Urine Drug & Specimen Validity Testing

SVT analyzes the urine specimen to ensure that it hasn't been tampered with or adulterated. Unlike actual urine drug testing which is deemed medically necessary to detect and quantify the presence of drugs in a patient's body, Medicare doesn't consider SVT medically necessary where its sole purpose is to validate the specimen since the SVT results aren't actually being used to manage the patient's treatment.

**Exception:** SVT is medically necessary in limited cases when it's used in combination with a urine drug test done on the same day for purposes of diagnosing certain conditions such as kidney stones or urinary tract infection. However, the latter cases are relatively rare, or at least CMS thinks they *should be*. So why are they being billed so frequently?

## Indications of Improper Billing

With that question in mind, the OIG audited $67+ million in Medicare Part B payments for SVTs billed in combination with urine drug tests, i.e., on the same dates of service, from 2014 through 2016. The findings: $66.3 million of the payments were improper. Those payments were received by 4,480 clinical labs and physician offices. The OIG report cited two reasons for the improper payments:

Providers' failure to follow existing Medicare guidance; and

The inadequacy of CMS system edits designed to prevent payment for SVTs billed in combination with urine drug tests, in spite of revised edits implemented in 2016.

The OIG urged Medicare contractors who made the $66.3 million in improper payments to implement better edits and make an effort to recover the money already spent.

## The Fallout

Many of the 4,480 labs and physician offices that received improper SVT payments have gotten a repayment request from their Medicare contractor. But for contractors, recovery isn't that simple. One problem is that the audit looks only at specific claim lines. Consequently, contractors must conduct medical review of the entire claim to determine whether it includes a relevant diagnosis code.

Meanwhile, some labs have decided to do their own internal audits and voluntarily self-disclose any improper SVT payments they identify. There have been at least

*Continued on page 10*

Enforcement Trends: CMS Orders Medicare Contractors to Go After Labs that Received Specimen Validity Test Payments , From Page 9

four such reported self-disclosure cases in the past month, each from the Ohio Valley region:

- $126,799 paid by The Northern Kentucky Center for Pain Relief (Jan. 24, 2019);
- $125,983 paid by VerraLab in Louisville, Kentucky (March 13, 2019);
- $111,706 paid by Wheelersburg Internal Medicine Group + Mohammad Mouhib Kalo, MD in Ohio (Feb. 6, 2019); and
- $69,776 paid by Medical Specialist of Kentuckiana, PLLC in Louisville (March 13, 2019).

# Labs IN COURT

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

## 56 Months' Jail for Lab Technician Caught in Texas Toxicology Scam

**Case:** A former toxicology testing company account rep pled guilty to conspiring with a medical clinic lab technician to steal patient identities and urine specimens from the clinic and send them to the testing company without a physician order or patient consent so they could pocket commissions and collection fees. Along the way, they forged patient consent signatures, falsified medical records and created registration forms and other fictitious documents to make it look like the unapproved toxicology screens were properly ordered. As a result of the scheme, Medicare was billed $836,788 between May and December 2015.

**Significance:** The account rep was sentenced to 56 months followed by three years of supervised release; in exchange prosecutors dropped the remaining 17 charges against him and the lab technician, who'll be sentenced on April 17. Each defendant will also pay $166,866 in restitution.

## Atlanta Medical Group Execs Jailed for $8.5 Million Allergy Testing Scheme

**Case:** The two owners of now defunct Primera Medical Group pled guilty to criminal charges for their role in billing insurers for allergy blood tests that weren't medically necessary, ordered by a physician or, in many cases, even performed. Details: Primera hired market research firms to pay fees to recruit privately insured patients to undergo allergy testing regardless of whether they had symptoms indicating the tests were medically necessary, generating over 4,500 claims seeking $8.5+ million from private insurers. The owners even fabricated false lab reports for tests that were never completed and sent them to not only insurers but also directly to patients, in one case sending phony results to the family of a 5-year-old girl suffering from an unknown reaction. Both owners were fined over $1.5 million and sentenced to 81 months and 93 months in jail, respectively, followed by three years of supervised release.

**Significance:** In addition to health fraud, the owners committed aggravated identity theft by billing insurers for the tests and allergy immunotherapy injections administered to nearly every patient using National Provider Identifiers of other doctors without their knowledge.

## Texas Scammer Gets 20 Years for Role in $50 Million Lab Test Ripoff

**Case:** The plot unfolded 10 years ago when a then 26-year-old woman and three co-conspirators set up 24 phony diagnostic testing centers in Houston. Offices were rented in 28 locations even though none of them actually saw any patients. To complete the charade, the offices were staffed with "seat warmers," i.e., young women whose only job was to answer the phones and keep out auditors, and who actually sat around and watched streamed movies all day. Meanwhile, fake diagnostic testing technicians, nurses and doctors were employed to act as a "rubber stamp" so that $50 million in tests could be billed to Medicare, Medicaid and private insurers. Fake technicians even visited supposedly homebound patients to carry out sham tests billed to home health care programs.

**Significance:** Three of the four co-conspirators (charges were dropped against the third after he was found mentally incompetent to stand trial) were convicted on not only health fraud but also money laundering charges in connection with efforts to hide the true owners of the test clinics. The ringleader was sentenced to 20 years in jail and three years of supervised release and ordered to repay almost $15.3 million as restitution. The other two defendants are awaiting sentence.

## Maryland Hospital Fined $457.2K for Free Support Services Kickbacks

**Case:** Union Hospital of Cecil County, Inc. has agreed to pay $457,213 for a pair of self-disclosed kickback violations, namely, paying remuneration to:

- Physicians in the form of free support services provided by a trio of physician assistants; and
- Cardiologists via free support services provided by a nurse practitioner.

**Significance:** The OIG didn't disclose any of the details of the arrangements, other than to say that the hospital self-disclosed them, which presumably resulted in a lighter penalty. Free or discounted support services from referral sources to physicians are, of course, a common form of illegal remuneration banned by the anti-kickback and Stark laws.

## Device Company Pays Nearly $20 Million to Settle MD Bribe Claims

**Case:** Former sales managers of Covidien LP filed a whistleblower suit accusing the firm of providing free or discounted marketing and practice development services to California and Florida physicians to get them to buy Covidien's ClosureFAST™ radiofrequency ablation catheters. In addition to kickback violations, Covidien violated the False Claims Act by billing Medicare and Medicaid for the devices, the claim alleges. Covidien denies the charges. But once the DOJ decided to pick up the case, it decided that discretion was the better part of valor and agreed to settle for $17,477,947, of which $3,146,030 will go to the whistleblowers. In addition, Covidien will have to pony up $1,474,892 to California and $1,047,160 to Florida to settle the related Medicaid claims.

**Significance:** Although Covidien is a medical device company, this case is also extremely relevant for labs. The Antikickback Statute ban on offering referring physicians free or cut-rate practice and marketing services, e.g., accounting, technology, EHR, consulting and other forms of support, also applies to labs.

## $1.99 Million Settlement for False Billing of Genetic Tests

**Case:** In a case that began as a whistleblower suit filed by two ex-employees, GenomeDx Biosciences has agreed to shell out $1.99 million to settle charges of improperly billing Medicare for its Decipher Biopsy which predicts the probability of prostate cancer metastasizing after surgery and classifies the tumor's aggressiveness. The feds claim that over a nearly two-year period, beginning in September 2015, the San Diego-based genetic testing company made

*Continued on page 12*

Labs In Court, *From Page 11*

claims for Decipher tests performed on patients who didn't have risk factors making the tests medically necessary. The whistleblowers will get $350K of the settlement.

**Significance:** Decipher, which is based on the level of expression for 22 RNA biomarkers involved in prostate cancer pathways, has gained favor with a growing number of payors, including Cigna. In 2015, Medicare approved coverage but only for a limited subset of patients, i.e., those with: i. pathological stage T2 disease with a positive surgical margin; ii. pathological stage T3 disease; or iii. rising prostate-specific antigen levels after an initial PSA nadir. The patients GenomeDx billed for allegedly lacked the risk factors spelled out in the coverage policy.

## Lab Settles Specimen Collection Fee Kickback Charges for $2.275 Million

**Case:** Cleveland HeartLab (CHL) has agreed to pay $2,275,094 after self-disclosing to the OIG that it paid remuneration in the form of payments to physicians and physician groups for collecting, processing and handling blood specimens. The offenses occurred during a four-year period between 2010 and 2014, three years before CHL was acquired by current owner Quest Diagnostics.

**Significance:** OIG Advisory Opinions and court cases, including the notorious Health Diagnostics Laboratory (HDL) case involving the payment of a $10 to $17 per test processing fee to physicians have made it abundantly clear that processing fee arrangements raise bright red flags under the Anti-Kickback Statute and Stark Law. (See Lab Compliance Advisor, Dec. 10, 2018, for more complete analysis of managing kickback risks associated with specimen processing fees.) More legally sound alternatives to help physicians manage the costs of specimen collection and processing include:

- Establishing a collection station near the offices of your physician clients; and/or
- Placing a phlebotomist or staff member compensated by your lab at fair market value within their facilities.