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Compliance Perspectives: Managing Kickback Liability Risks of Specimen Processing Fees

It's common practice for labs to pay physicians a fee for collecting and processing blood, urine, tissue, and other specimens from the patients they refer to your lab for testing. While this might seem like a normal part of business and practice, it can also get you into big legal trouble.

Kickback Red Flags

The federal *Anti-kickback Statute* (AKS) and *Stark Law* ban labs from offering or paying anything of value to physicians to encourage or reward them for referring patients covered by Medicare, Medicaid, and other federal health programs. So, any time a lab pays a fee to a referring physician, it raises a red flag.

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Case of the Month: ACA Constitutionality Is Back in Play & This Time It May Get Taken Down

After a series of court setbacks, Republicans challenging the constitutionality of Obamacare, aka, the *Affordable Care Act* (ACA) are back at it. And this time they got a good shot to win. Here's a look at the latest case and what it means for the future of ACA and the insurance markets.

Beating a Dead Horse?

The issues in this new challenge are the same as before, namely, the constitutionality of the individual mandate and entire ACA. Haven't we been down this road before? After all, six years ago, the U.S. Supreme Court upheld the individual mandate as constitutional. *The reasoning:* The mandate plus the penalty for not having health insurance constitute a federal tax and thus a constitutional exercise of the U.S. Congress's constitutional powers to tax [*National Federation of Independent Business v. Sebelius*].

Things Are Different This Time

What's changed since *Sebelius?* On Dec. 20, 2017, Congress passed the *Tax Cuts and Jobs Act* establishing the mandate penalty at $0 starting in 2019. The plaintiffs in the new case, among them 20 Republican state attorneys general, contend that a zero penalty is *not* a tax and thus no longer supportable

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The HDL Case

The 2015 Health Diagnostic Laboratory (HDL) case is the poster child for abusive specimen processing and handling fee arrangements. The case began when a whistleblower filed a qui tam lawsuit accusing HDL and its business associate Singulex of paying kickbacks to physicians in the form of processing fees of up to $10 to $17 per test in exchange for orders of medically unnecessary blood tests. HDL then compounded its liability by subsequently billing those ill-gotten tests to Medicare and TRICARE, thereby bringing the *False Claims Act* into play.

> The moral is *not* to avoid specimen processing fee arrangements with referring physicians.

By the time the dust had cleared, HDL paid $47 million and Singulex $1.5 million to settle kickback and false claims charges. And in July 2018, the individual principles of both companies were convicted and fined another $114 million for their role in the scheme.

Kickbacks Don't Have to Be Deliberate

Those who would deliberately abuse processing and handling fees as a disguise for kickbacks deserve to be prosecuted and punished. The problem is that well-meaning labs—like yours!—can cross the line inadvertently and without intending to.

Thus, for example, in 2005, the OIG issued an Advisory Opinion warning a lab that paying a referring physician a fee of $3 to $6 per patient for collecting specimens from Medicare patients—using blood drawing supplies supplied at no charge by the lab—raised concerns under the AKS.

Keeping Your Specimen Processing Arrangements on the Up and Up

The moral is *not* to avoid specimen processing fee arrangements with referring physicians. In addition to being clinically effective, such arrangements are perfectly legal as long as you structure them the right way. The good news is that the OIG has explained how to do that.

In 2014, the OIG issued a Special Fraud Alert addressing "Specimen Processing Arrangements," which the agency defines as those typically involving services such as collecting the blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packaging the specimens so they're not damaged during transport.

The Alert lists characteristics that the OIG deems as a suspect arrangement. *Bottom Line:* Being aware of and diligent in applying the OIG smell test criteria is the key to ensuring your own specimen processing arrangements comply with AKS and Stark restrictions. *Instructions:* Vet your arrangements by asking the following YES/NO questions about the fees you're paying. If you can't answer NO to *all* of the questions, you have a potential problem and should think twice before proceeding with the arrangement. The more YES responses, the bigger your problem.

G2CA

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Does/Is the specimen processing fee you propose paying to the referring physician:

- Exceed fair market value?
  ☐YES ☐NO
- Calculated on a per-specimen, per-test, per-patient, or some other method that takes into account the value or volume of referrals?
  ☐YES ☐NO
- Cover services for which payment is also made by a third party, such as Medicare?
  ☐YES ☐NO
- Made directly to the ordering physician rather than to the ordering physician's group practice that employs the physician and actually bears the cost of collecting and processing the specimen?
  ☐YES ☐NO
- Offered on the condition that the physician order either a specified volume or type of test or test panel, especially if the panel includes duplicative tests, e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information, or tests that otherwise are not reasonable and necessary or reimbursable?
  ☐YES ☐NO
- Offered on the condition of a certain number or type of test orders, especially where the tests are duplicative, not medically necessary or not reimbursable?
  ☐YES ☐NO
- Cover services that are actually performed by someone placed in the office by the lab?
  ☐YES ☐NO

Final Caveat: One tactic that will not work in managing your liability risks is limiting the payment arrangement to nonfederal health care program patients. The amount paid for the nonfederal program patients could still serve as a financial incentive to refer the federal health care program patients to the lab, warns the OIG.

TOOL: Model Specimen Processing Fees Compliance Policy

Here's a Model Policy your lab can adapt to ensure that specimen processing fee arrangements with referral sources don't violate the Anti-Kickback and Stark laws:

SPECIMEN PROCESSING FEES COMPLIANCE POLICY

1. PURPOSE

The purpose of this Policy is to ensure that Specimen Processing Fee Arrangements that XYZ Laboratories enters into with Referral Sources provide for compensation that is consistent with Fair Market Value in accordance with the requirements of Medicare, Medicaid, TRICARE and other federal health care programs and payers.

2. DEFINITIONS

For purposes of this Policy:

- **"Fair Market Value"** means the value, or range in value, in arm's length transactions, consistent with the compensation that is the result of bona fide bargaining between well-informed parties to an agreement who are not otherwise in a position to generate business for the other party at the time of the agreement;

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- **"Referral Source"** means a physician or other person or entity that can order or influence or recommend the ordering of diagnostic tests to XYZ Laboratories for testing;
- **"Remuneration"** means anything of value, including but not limited to cash, items or services;
- **"Specimen Processing Fee Arrangement"** means one in which XYZ Laboratories pays a Referral Source a fee for collecting, processing or packaging blood, urine, tissue and other patient samples for testing, including but not limited to services such as collecting blood specimens, centrifuging specimens, maintaining specimens at a particular temperature and packaging the specimens so they are not damaged during transport.

3. POLICY

XYZ Laboratories shall only enter into a Specimen Processing Arrangement with a Referral Source if it can be objectively demonstrated that the terms of the Arrangement are consistent with Fair Market Value, not intended to induce the referral of patients or to generate other business between the parties, and consistent with all other terms of applicable XYZ Laboratories policies.

4. FAIR MARKET VALUE VERIFICATION ASSESSMENT

All Specimen Processing Fee Arrangements with a Referral Source must be cleared by the XYZ Laboratories compliance officer or other authorized official for verification that Remuneration provided under the Arrangement reflects Fair Market Value. In making such determination, the XYZ Laboratories compliance officer or other authorized official will rely on the following resources:

- Medical Group Management Association ("MGMA") Physician Compensation Surveys and other applicable physician payment resources;
- Medicare or Medicaid Fee Schedule rates for services provided under the Arrangement;
- Workers' Compensation Fee Schedules for services provided under the Arrangement;
- Competitive bids submitted under a formal RFP process seeking to contract out the services provided under the Arrangement; and
- A report or recommendation from an outside, qualified consultant identifying the Fair Market Value for the services provided under the Arrangement;
- Any other surveys, materials, opinions or data applicable to identifying the Fair Market Value for the services provided under the Arrangement.

5. PROHIBITED PRACTICES

Remuneration paid to Referral Source under a Specimen Processing Fee Arrangement shall not:

- Be calculated on a per-specimen, per-test, per-patient or other method that takes into account the value or volume of referrals;
- Cover services for which payment is also made by a third party, such as Medicare;
- Where the Referral Source is part of a physician group practice, be made directly to an ordering physician but instead to the group practice that employs the physician and bears the cost of collecting and processing the specimen;
- Be offered on the condition that the Referral Source order either a specified volume or type of test or test panel, especially if the panel includes duplicative tests, e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information;
- Be offered on the condition of a certain number or type of test orders, especially where the tests are duplicative, not medically necessary or not reimbursable;
- Cover services that are actually performed by personnel placed by XYZ Laboratories in the offices of the Referral Source.

OIG Work Plan Monthly Review: September 2018

Neither of the two new OIG Work Plan items directly impacts labs but both address areas of national concern and have potential long-term implications on at least some labs.

1. Follow-Up Review of Head Start Grantee

Issue: A community-based, not-for-profit organization was awarded a Head Start grant to provide early childcare, social services, education, health, nutrition, and related services to children and their families at three centers in the Bronx, New York. The Administration for Children and Families requested that OIG conduct an audit of this grantee because of its high risk of noncompliance with federal compliance.

OIG Action: The OIG will conduct an audit and determine whether the grantee claimed Head Start costs that were allowable under applicable federal regulations and the terms of the grant. The review will focus on two specific areas: the related-party transaction and restitution of embezzled funds.

2. Review of Opioid Use in Indian Health Service

Issue: Opioid abuse and overdose deaths are at crisis levels in the United States, with approximately 49,000 Americans dying from opioids in 2017, an increase from more than 42,000 in 2016.

OIG Action: Consistent with previous work in Medicare Part D and Medicaid, OIG will conduct a review to determine the extent to which beneficiaries are receiving extreme amounts of opioids through Indian Health Service (IHS), an agency within the Department of Health and Human Services (HHS) responsible for providing federal health services to Native American Tribes and Alaska Native people. It will also look at IHS-employed prescribers and IHS-run pharmacies that have questionable prescribing or dispensing patterns. Additionally, the review will determine how IHS prevents and detects opioid misuse or abuse, as well as how it enforces opioid-related policies.

Labs IN COURT

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

Free Testing Supplies to Physicians Costs Massachusetts Lab $1.374 Million

Case: A federal court ordered Calloway Laboratories, Inc. to pay $1,374,058 to settle claims of falsely billing Medicare and TRICARE for urine drug tests over a six-month period in 2014. As part of the settlement, the now defunct Woburn,Mass.,-based lab admitted to offering free testing supplies to physicians in exchange for testing referrals. What would have been simply a kickback offense became a *False Claims Act* when Calloway subsequently billed Medicare and TRICARE for those tests.

Significance: The Medicare and TRICARE civil judgment is the latest chapter for a lab involved in what the Mass. Attorney general described as "one of the most egregious Medicaid abuses our offices has handled." In 2013-14, Calloway's chief operating officer and three other individuals were convicted of using straw companies to funnel money bribes to employees of sober houses to generate urine drug testing referrals for patients covered by the MassHealth Medicaid program.

Texas Lab, Owner Get 15-Year Exclusion for Medicare Mileage Swindle

Case: What would *you* do if your bill for a $43 blood test included a $1,500 travel fee? The patient who actually received such a bill from Texas lab BestCare complained to the government. The subsequent investigation found evidence that BestCare billed Medicare for over $10 million in false mileage for miles not traveled by a technician. After refusing to toss the case without a trial, the court found the lab guilty of *False Claims Act* violations and fined it $30.5 million. And on Aug. 17, an Administrative Law Judge upheld the OIG's decision to exclude BestCare and its owner from all federal health programs for 15 years.

Significance: Under Medicare rules, labs can charge $1 per mile for transporting a specimen as long as a technician travels along. The lab committed two offenses:

- Billing travel mileage for specimens shipped on commercial airlines during flights in which no technician was present;
- Imposing a separate $1 per mile travel fee for each specimen transported collectively rather than prorating mileage among the individual specimens.

Jail for Urine Drug Testing Kickback Co-Conspirators

Case: Urine samples produced by patients of a Maryland-based pain clinic were a billables gold mine for a Jersey City testing lab, well worth the $1.37 million in kickbacks it ultimately paid to secure them. The lab CEO was sentenced to a year and a day in jail, ordered to forfeit $241,600 and fined $5,000. His marketing consultant and co-conspirator got three months' supervised release in home detention, a $23,400 forfeit order and a $4,000 fine.

Significance: The defendants seem to have gotten a pretty good plea deal considering the scheme. According to the court documents, the parties agreed to split the profits 50/50, with the marketer getting a 5% cut for putting the deal together. Among the three clinic defendants, one was just sentenced to eight years in jail (the extra sentence reflecting the extra crimes of tax evasion and fraudulent billing of anesthesia), one died and the other is a fugitive.

Aetna Sues Manager of Oklahoma Rural Hospital for Lab Test Ripoff

Case: People's Choice, a management firm specializing in turning around financially strapped hospitals, is being sued by Aetna for using an Oklahoma rural hospital client to carry out an elaborate lab billing fraud. In a bid to keep Newman Memorial Hospital afloat, People's Choice sent blood and urine samples to other labs and falsely claimed that Newman processed the tests, the suit contends. Aetna says that over a 16-month period, it lost $21.6 million on over 10,000 lab tests, in some cases paying $2,250 for tests it thought were done at Newman rather than the $120 it would have paid a larger lab to do the test. People's Choice denies the allegations and has already settled with Newman.

Significance: False billing of lab tests has been a perennial lightning rod for litigation. What's changing, however, is not the defendant but the plaintiff. What we're seeing is the plateau-ing of federal and state enforcement against labs accompanied by a steadily growing percentage of civil lawsuits by private parties, especially insurance companies. Because they charge premium rates, rural outreach hospitals are often at the center of these cases.

Florida Lab Owners Convicted for Role in Notorious Drug Distribution Scheme

Case: The two brothers who own a Palm Beach lab pleaded guilty to health care fraud for their role in the illegal drug distribution conspiracy carried out by notorious sober home operator Kenny Chatman. The brothers, who face up to 10 years in prison, paid kickbacks to rehab centers operated by Chapman for urine samples used to perform medically unnecessary drug tests that were subsequently billed to insurance companies at high rates. Their lab, Smart Lab, also faces charges carrying potential fines of up to $500K.

Significance: If you've never heard of him, Kenny Chatman has been described by Florida prosecutors as not the biggest illegal drug treatment provider in the state, only the most dangerous. Chatman locked up drug addicts that came to his sober home for help, taking their food stamps, and even forcing them into prostitution. Addicts with insurance were forced to produce three urine samples per week for testing. Several died of overdoses in the homes. And Chatman made millions in the process. Now that the kingpin is in jail for 27 years for health fraud, money laundering and sex trafficking, prosecutors have begun targeting his lieutenants.

ACA Constitutionality Is Back in Play & This Time It May Get Taken Down, From Page 1

as an exercise of Congressional taxing powers. And since the individual mandate isn't severable from the rest of the ACA, the entire ACA should be struck down as unconstitutional.

The other big difference is who's leading the defense. Needless to say, the Trump Justice Department is far less dedicated to defending the ACA than its predecessor. In fact, the DOJ agrees that 16 parts of the ACA should be struck down. Where it differs from the plaintiffs is in deeming two parts of the law constitutional and worth defending. But with such a lukewarm endorsement, it's hardly surprising that attorney generals from 16 states and the District of Columbia have intervened in the lawsuit to bolster the ACA's defense.

The Texas Showdown

The venue for the new case, *Texas v. United States*, is the federal district court in the Northern District of Texas. On Sept. 5, Judge Reed O'Connor held a hearing to deal with the plaintiffs' request for a preliminary injunction (PI), i.e., court order barring enforcement of the law pending the outcome of the case. A PI would effectively freeze the ACA unless and until either an appeals court overturned it or the court ultimately ruled on the merits in favor of the law's constitutionality.

The good news for ACA advocates is that getting a court to issue a PI is a pretty stiff task. To pull it off, the plaintiffs must prove four things:

1. They'll likely to succeed on the merits of the case;
2. They'll likely suffer "irreparable harm" if the PI isn't granted;
3. The balance of equities favors their argument;
4. Granting the PI is in the public interest.

What's At Stake

Obviously, there's a lot on the line in both the short- and long-term:

Short-Term: If Judge O'Connor did decide to grant the PI, it would create a hot mess in insurance markets. The DOJ itself noted that a preliminary injunction could introduce "chaos in the insurance markets" and asked the court to limit any declaratory ruling to the constitutionality of the individual mandate beginning in 2019. The DOJ also noted the need for additional briefing on the timing and impact of an injunction on state insurance markets, as well as the need to potentially issue new regulations and address the multi-year process by which insurers must get their products approved for sale.

Long-Term: Invalidating the entire ACA would adversely impact:

- Protections for people with pre-existing conditions;
- ACA Medicaid expansion;
- Children under 26 who get insurance through their parents' plan;
- Annual and lifetime coverage limits; and

- Caps on out-of-pocket expenses.

Accordingly, the DOJ has asked the court to defer any ruling on severability, i.e., whether invalidation of the mandate takes down the entire ACA, until 2019 after the close of the next open enrollment period and mid-term elections.

More to Come

Don't expect any immediate resolutions one way or the other. No matter how the court rules, an immediate appeal to the Fifth Circuit of Appeal is all but assured. And no matter how the Fifth Circuit ruled, the U.S. Supreme Court will be asked to intervene—although there's no guarantee it'll accept the case.

Dissolution: The Final Act of the Theranos Tragedy

Just five years ago, Theranos was a Silicon Valley sensation with a valuation of over $9 billion. While black turtlenecked Elizabeth Holmes supplied the charisma, the heart of the Theranos phenomenon was its finger-stick blood test technology offering not only accuracy but groundbreaking convenience.

But it was all a mirage. And now it's coming to an end.

As a result of testing issues, an agreement with Walgreens—which had been the company's steppingstone to the consumer market—unraveled.

Faulty Technology

The technology proved unreliable. In fact, Theranos often used analyzers from other companies to test consumer blood samples. What's more, Theranos modified some of those analyzers in ways that were not approved by the manufacturers or consistent with federal health agency guidelines. Because of the modifications, test results were often inaccurate.

Financial Fallout

As a result of testing issues, an agreement with Walgreens—which had been the company's steppingstone to the consumer market—unraveled. The drugstore chain sued the company for breach of contract and was awarded damages.

In April 2017, Theranos settled charges with CMS agreeing to a $30,000 fine and two-year Medicare exclusion.

Determined to carry on, Theranos refocused its business, shedding its CLIA lab testing and concentrating on technology. Layoffs followed. The company, which once reportedly employed 800, was down to fewer than 25 employees earlier this year.

Criminal Conduct Alleged

Things went from bad to worse.

According to *The Wall Street Journal*, Holmes and her ex-boyfriend, Ramesh "Sunny" Balwani, who served as Theranos president and chief operating officer until he retired from the company in May 2016, have been in-

dicted on nine counts of wire fraud and two counts of conspiracy to commit wire fraud.

If convicted of charges, which allege that they defrauded investors out of hundreds of millions of dollars, while also defrauding doctors and patients, Holmes and Balwani each faces up to 20 years in prison and a fine of $250,000, plus restitution to those found to have been defrauded—on each count.

Corporate Dissolution

Against this backdrop, it perhaps comes as no surprise that in an email to shareholders the company has now announced it has ceased operations and will formally dissolve.

Theranos indicates that before arriving at this decision, it pursued a sale. However, after reaching out to more than 80 potential buyers, no deal materialized.

The company owes at least $60 million to unsecured creditors, according to the email. As part of its dissolution, Theranos will distribute its remaining cash, estimated to be approximately $5 million, to unsecured creditors.

Stark Relief: Change Seems Imminent but Less Dramatic than Industry Wants

CMS is giving serious indications of its willingness to entertain Stark Law relief. Back in June, CMS issued a Request for Information (RFI) seeking public comments and suggestions on changes to relieve the Stark Law's "undue regulatory impact and burden." (See *GCA*, July 16, 2018.) Comments closed on Aug. 24. And if CMS takes those comments to heart, it means changes are on the way. But don't get too excited just yet...

Main Theme: Stark Is Out of Sync with Modern Health Care

One of the noteworthy things about the comments is who did not participate in the process, namely, consumer advocate groups who would likely oppose any significant changes to Stark. In their absence, the vast majority of comments came from industry and other groups determined to change Stark.

So, it's hardly surprising that comments overwhelmingly skewed in favor of revamping Stark. While the intent of preventing inappropriate physician referrals remains valid, commentators were all but unanimous in saying that Stark needs to change to reflect current medical industry practices. The law was adopted at a time when Medicare services were provided on a fee-for-service basis and health care was provided in distinct silos, several noted. Those conditions no longer pertain today. In addition, modern industry payment policies and reimbursement models currently address the referral risks that Stark was meant to prevent.

3 Things the Commentators Want

Among the notable comments and suggestions:

1. New Value-Based Payment Exception

Create a new Stark exception for value-based payment methodologies that allows hospitals to incentivize physicians for selecting the most efficient and effective care options by sharing a portion of any cost savings when overall costs of care are reduced.

2. Clarify & Expand Current Exceptions

CMS needs to clarify and expand some of the existing exceptions for value-based payment. For example, several commentators suggested expanding the personal services arrangement exception by removing limitations on its applicability to commercially insured patients.

3. Clarify Key Definitions

The comments cite several important Stark definitions that are extremely difficult to decipher—and thus comply with—that CMS needs to clarify or simply redefine, including:

- "fair market value";
- "financial relationship"; and
- "remuneration".

OIG Also Getting in on Kickback Relief

CMS isn't the only agency contemplating modernizing the health care kickback laws. On Aug. 28, the OIG published its own Request for Information seeking comments on how to modify or add new safe harbors to Stark's cousin, the Anti-Kickback Statute to "foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse." Deadline to comment: Oct. 26.

What Happens Next?

After comments, the next step after comments in the new rulemaking process is for CMS to propose new rules based on the comments. This is unlikely to happen quickly, notes Nashville health care attorney Bradley J. Sayles. And any new rulemaking that CMS does propose must be submitted for 60 days of public comment. Thus, even if CMS fast tracks the process, it'll take at least six months for permanent changes to be made. And even that seems overly optimistic. Sayles suggests a best-case scenario of one year.

Takeaway: Don't Get Too Excited

Sayles also throws cold water on the hopes for sweeping change. Real change can only happen legislatively, he contends. The best CMS can do is revamp definitions to remove ambiguities and create more certainty. It can also pitch new exceptions as it has in the past. But previous recommendations for Stark changes fell on deaf ears and Sayles says there's no guarantee the outcome would be any better this time around.