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INSIDE THIS ISSUE

Enforcement Trends: Feds Targeting Commercial & Private-Pay, Not Just Medicare Fraud

Risk of federal prosecution for health fraud and abuse applies only when you deal with Medicare, TRICARE or other federal health programs.

Right?

Wrong! 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.

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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HIPAA: New HIPAA Penalties System Rewards Labs that Try to Comply

New HHS rules significantly increase the amount of money your lab can save by making diligent and demonstrable efforts to prevent HIPAA violations even when those efforts don't succeed. We're referring to the new HHS system of basing maximum HIPAA penalties on "level of culpability" set out by the agency in its April 26 Notification of Enforcement Discretion (Notice). Here's the low down.

How HIPAA Penalties Are Determined

The *Health Information Technology for Economic and Clinical Health Act* (HITECH Act) establishes a four-tier system for

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Enforcement Trends: Feds Targeting Commercial & Private-Pay, Not Just Medicare Fraud, *from page 1*

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: The Forest Park Case

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 at least three recent cases of federal prosecution for commercial fraud committed by providers. 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

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in exchange for private patient referrals in violation of the AKS. The more surgeries doctors referred, the more they earned.

Had it been just about the AKS, this would have been pretty routine prosecution. But what makes the Forest Park 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 conduct interstate commerce for the purposes of carrying on unlawful activity under another statute—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 other 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: Although it's likely to be appealed, the Forest Park case is being hailed as a significant victory for the DOJ and a wake-up call for providers, including labs. While it may turn out to be nothing more than an outlier, as was noted during the trial, the kinds of marketing agreements involved in the case are in fairly common use within the health care industry. And that creates the potential for more commercial fraud prosecutions, both inside and outside Texas. Bottom Line: Risk of medical fraud prosecution is creeping beyond the bounds of Medicare and into private commercial arrangements.

Google This: Labs Partner with Tech Giant

In recent months, several diagnostic companies have announced alliances with Google, and all involve Google Cloud Platform.

Here is how four companies are using Google's technology.

Genomenon

Genomenon, a genomic search company, is partnering with Google to offer genomic data technology on Google Cloud Platform. Genomenon's Cited Variants Reference (CVR) data will be a public dataset available in BigQuery, Google Cloud's big data and machine learning data warehouse, for use in genomic applications.

The Cited Variants Reference is generated from Genomenon's Mastermind genomic database, a comprehensive index of genomic literature. With more than 4.1 million genomic variants found in medical literature, each

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variant is annotated with a citation count based on the number of scientific publications mentioning the variant, along with a link into the Mastermind Genomic Search Engine to view full search results for those articles. The CVR is designed to help clinicians and researchers prioritize and scale their genomic interpretation.

Parabricks

Parabricks, a provider of GPU-based bioinformatics software solutions for analyses of next-generation sequencing data, recently collaborated with Google as a tech partner and launched its accelerate, deep learning based product suite for primary and secondary analysis on Google Cloud Platform.

The Parabricks solution reduces the time and cost required to go from raw sequencing data to variants for a whole genome, producing variant calls in less than an hour compared to the standard 30 hours when running the same industry standard pipeline on HPC CPU clusters. The suite provides push-button operation, 100% reproducibility, and containerization of the latest secondary analysis tools by bioinformaticians worldwide.

WuXi NextCODE

WuXi NextCODE, a genomic information company using sequence data to improve health, has partnered with Google to deliver comprehensive genomics capabilities to partners and customers worldwide.

The alliance calls for Google to host WuXi NextCODE's core suite of capabilities, including GORdb, WuXi NextCODE secondary analysis, its Sequence Miner case-control research application, and its Clinical Sequence Analyzer clinical interpretation system. At the same time, key Google genomics and research tools will be integrated and deployable in tandem with the WuXi NextCODE platform, beginning with the DeepVariant secondary analysis pipeline, alongside other open-source analysis pipelines and tools available through Google Cloud Platform.

IntegraGen

IntegraGen, a company specializing in the decoding of the human genome with a focus on producing interpretable genomic analysis for academic and private laboratories, is collaborating with Google to integrate its advanced genomic analysis tools, Sirius and Mercury, into Google Cloud Platform.

The arrangement will enable widespread online availability of data, rapid data transfer, and enhanced data security to clinicians and researchers utilizing these analytical tools.

Why Google Cloud Platform

Best known for its search capabilities, Google has, with relatively little fanfare, been building a presence in healthcare, including the lab industry.

Google's strength in search, security, and compliance makes partnerships a natural fit. Speed also makes the solution attractive.

Companies in a wide range of industries are using Google Cloud Platform in myriad ways, and speed is a factor for companies in many industries.

However, for labs, as for healthcare in general, speed has the potential to result in more lives saved. Given the importance of speed in this regard, along with time-to-market financial advantages, it's likely other diagnostics companies searching for an alliance will turn to the tech giant. Indeed, the outlook for Google Cloud Platform and the lab industry appears bright.

Case of the Month: FDA Issues Warning Letter for Unapproved Changes to Approved Assay

As a rule of thumb, FDA approvals are a snapshot applicable only to the product as it exists at the time of review and approval. So, when the product undergoes significant changes, it often triggers the need for new clearance. A California device maker just learned that lesson the hard way.

What Happened

Last year, the FDA inspected Union City, CA-based Abaxis, Inc. before it was acquired for $2 billion by animal health company Zoetis. And based on the inspection results, it sent Abaxis a warning letter, i.e., a notification of violations documented during inspections of the company's facilities to which the company must respond. The April 12, 2019 warning letter contends that:

- Abraxis' Piccolo Potassium assay, used with the Piccolo Xpress chemistry analyzer, is a Class III device lacking premarket approval; and
- Evidence exists that the assay is misbranded.

Specifically, FDA concluded that Abaxis changed the assay without bothering to inform the agency. According to the letter, "your firm made changes that affected the potassium assay calibration specifications and ultimately changed the performance of the device, as demonstrated by customer complaints."

Changes to calibration set points, the FDA claims, is by its nature a change to the performance specifications that raises new issues of safety and effectiveness since a falsely low potassium result could lead to serious adverse consequences such as delay in treatment or no treatment for hyperkalemia. As a result, the change requires a new 510(k) premarket notification.

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Abaxis' Response

Abaxis has responded to the FDA's concerns on five separate occasions but has been unable to talk the agency out of requiring a new 510(k). According to the FDA, none of the five submissions assessed "whether the modifications could have significantly affected the safety or effectiveness."

The warning letter, of course, escalates the situation by giving Abaxis 15 business days to detail, in writing, the steps it took to fix the violations and stop similar problems from occurring again. If the corrective actions could not be completed within the 15 business days, Abaxis had to give an explanation for the delay, and a time frame for when the corrective actions would be completed.

News: DNA Testing at the Border

The Department of Homeland Security (DHS) is piloting a DNA testing program at the U.S.-Mexico border.

The program aims to establish "DNA-based family relationship (kinship) verification to improve immigration efficiency for legal kinship applicants, reduce kinship fraud, provide for family reunifications, and conduct DNA watch list checks," according to the DHS website.

Rapid Results

It will strive to do this through a process known as Rapid DNA. ANDE, a company founded based on pioneering research conducted at MIT, is the test provider.

ANDE's products are based on a series of enabling microfluidic and molecular biology technologies developed for sample preparation and DNA purification, rapid thermal cycling, highly multiplexed amplification, focused DNA sequencing, optical detection of DNA sequences, and nucleic acid separation and detection. What makes the company's solutions different is that they have been designed for use by non-technical operators outside the laboratory. The system being used at the border was developed in 2009, when ANDE was awarded the contract for a competitive R&D program sponsored by a consortium of federal agencies, including the Department of Defense, Federal Bureau of Investigation, and DHS. The result was the development of an automated rapid human DNA identification capability that minimizes analytical complexity and user manipulations for field-forward biometric and forensic applications, with the ability to deliver a fully automated and integrated field-deployable system that rapidly generates human DNA IDs with no user manipulations after inserting a sample into the system.

The ANDE system is currently used by law enforcement professionals worldwide.

Border Control Process

At the border, migrants who are suspected of posing as families to gain asylum will be asked to take DNA tests, which involve swabbing their cheeks and the cheeks of all accompanying children. The ANDE system will process the samples in a small portable machine and return DNA results in 90 minutes.

"In the last year, immigration officials said they've identified about 3,100 people who lied about being part of a family or claimed someone who was over 18 years old was a child. That number represents 1% of the 256,821 family units apprehended at the southern border during that same period."

The test is said to be voluntary, and a consent form must be signed prior to testing. Nevertheless, questions remain. Will non-English speaking people understand what they are consenting to? What happens if they refuse to take a DNA test?

Opponents of the process raise additional valid points, including that a family does not always involve biological relationships. By focusing on DNA matching, "nontraditional" families, which have arguably become traditional, may be separated.

Others cite statistics, including those shared in a recent BuzzFeed article: "In the last year, immigration officials said they've identified about 3,100 people who lied about being part of a family or claimed someone who was over 18 years old was a child. That number represents 1% of the 256,821 family units apprehended at the southern border during that same period."

Despite opposition, DHS is moving forward with the pilot DNA testing program. Whether it will be widely implemented remains to be seen.

Medicare Coverage: NGS Testing of Early-Stage Cancer Patients Is Back in Play

The reimbursement outlook for those who provide next generation sequencing (NGS) testing to early-stage cancer of Medicare patients with hereditary risks is far brighter today than it was a few weeks ago. Late last year, CMS issued a National Coverage Determination (NCD) that would have barred Medicare from paying for such testing. But after pushback from lab industry and other healthcare organizations, CMS has decided to reopen the NCD.

The Original NCD

Before the new NCD, many Medicare Administrative Contractors (MACs) had issued local coverage determinations (LCDs) providing for coverage of NGS-based genetic testing to screen early-stage cancer patients for mutations associated with inherited cancer syndromes like BRCA mutations and Lynch syndrome. The new NCD wasn't expected to have any impact

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Labs IN COURT

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

New York Breaks Up Massive $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 which 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 opioid addicts, massive overbillings and kickbacks involving thousands of medically unnecessary urine tests which were sent to Florida-based labs for analysis.

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.)

WV Hospital & Marketer Accused of Elaborate Kickback Scam

Case: A new DOJ lawsuit accuses a West Virginia non-profit hospital and its business consultant of seeking to dominate the Ohio Valley market by bribing physicians for referrals. The scheme began in 2005, according to the complaint, when Wheeling Hospital hired R&V Associates to turn around its sagging financial fortunes. The plan: Enter into contracts providing beyond market value compensation to the region's leading OB/GYN, radiology oncologists, cardiologists and pain management physicians for referring patients to the Hospital. As a result of these deliberate Antikickback Statute and Stark Law violations, the Hospital went from $50 million in losses to massive profits.

Significance: The complaint, which arose from a 2017 whistleblower lawsuit, details the contractual arrangements with the physicians who eagerly accepted the millions of dollars' worth of overpayments even though they knew it was illegal, and how R&V and the Hospital carefully tracked individual physician referral records and adjusted their compensation accordingly. Meanwhile, the Hospital has filed a breach of fiduciary lawsuit against its former executive VP, who's charged with carrying out the scheme with R&V.

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Urgent Care Centers Settle E/M Upcoding Charges for $2 Million

Case: The owners/operators of CareWell urgent care centers in Massachusetts and Rhode Island have agreed to shell out $2 million for improper coding of Evaluation and Management services. CPT code selection for E/M services is based on the number of body systems a provider must evaluate to diagnose a patient and who does the examination, e.g., nurse practitioner or physician. CareWell is accused of falsely inflating the level of E/M services performed and failing to properly identify who provided them. The whistleblower who brought the initial claim will get 17% of the recovery.

Significance: The part of this case that's relevant to labs are the alleged methods CareWell used to carry out the upcoding scheme, which are analogous to things labs have been charged of doing to inflate coding for testing services, including:

- Requiring medical staff to examine and document at least 13 body systems during medical inquiries and 9 systems during physical exams regardless of patients' actual complaints;
- Uploading encounter plan templates onto electronic medical records software asking "yes/no" questions about particular body systems that medical personnel had to ask each patient regardless of whether those questions were medically necessary; and
- Programming the template to list "no" as the default answer to any question that wasn't asked to make it look like the particular body system to which the question related was examined.

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on those LCDs because the MACs actually asked CMS to issue it for NGS testing of beneficiaries with *advanced* cancer; the request was also limited to a somatic-based test.

But CMS issued an NCD that it instructed MACs to apply to not just somatic but also germline NGS testing. And because an NCD supersedes an LCD, the agency's no-coverage determination would have rendered Medicare early-stage cancer patients with a genetic predisposition based on family history or other acceptable criteria ineligible for NGS-based testing.

The Industry Pushback

The response from industry was immediate and potent. In a Jan. 31 letter to CMS administrator Seema Verma, a group of over 60 healthcare companies and organizations including the American Clinical Laboratory Association (ACLA) joined over 60 health care companies and organizations calling on CMS to revise the NCD. Denying NGS testing to early-stage cancer patients with hereditary risks would adversely impact cancer patient care and outcomes, the letter argued.

CMS Reopens the NCD

The pushback seems to have worked. On April 29, CMS released a tracking

sheet announcing that it has decided to reopen the NCD. But the tracking sheet also emphasizes that CMS will only reconsider the evidence available for tests of germline mutations to identify patients with hereditary cancer who may benefit from targeted treatments based on their test results.

What Happens Next

Although it's still unclear how or even if CMS will revise the NCD, we do at least have a pretty firm idea of what the timetable will be:

- **May 29:** Public comments on the NCD close;
- **Oct. 29:** Due date for CMS to issue a proposed decision memo on the NGS;
- **Jan. 27, 2020:** CMS to issue final version of NCD.

HIPAA: New HIPAA Penalties System Rewards Labs that Try to Comply, *from page 1*

determining minimum and maximum civil monetary penalties (CMP) for HIPAA violations. The tiers range by severity, as illustrated by Table 1:

Table 1. The Old 4-Tier HIPAA Penalties System

Tier	Description	CMP Range
1	Violator didn't know and wouldn't have known through the exercise of reasonable diligence of HIPAA violation	$100 per violation up to maximum of $25,000 per calendar year
2	Violation due to reasonable cause, not willful neglect	$1,000 per violation up to maximum of $100,000 per calendar year
3	Violation due to willful neglect that's timely corrected	$10,000 per violation up to maximum of $250,000 per calendar year
4	Violation due to willful neglect that's not timely corrected	$50,000 per violation up to maximum of $1,500,000 per calendar year

When it implemented the HITECH Act back in 2013, however, HHS viewed the penalty provisions as "conflicting" and decided that the highest annual cap of $1.5 million under tier 4 should apply to *every* tier. Despite criticism, HHS held the line and insisted "that the penalty amounts are appropriate and reflect the most logical reading of the HITECH Act."

The New 'Level of Culpability' System

It took nearly five years, but HHS has finally seen the light. In the Notice, HHS announced that it's changed its position and will now follow the original intent of the HITECH Act by basing the potential range of penalties on the violator's level of culpability and efforts to comply. Table 2 summarizes the new "level of culpability" system.

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HIPAA: New HIPAA Penalties System Rewards Labs that Try to Comply, *from page 11*

Table 2. The New "Level of Culpability" HIPAA Penalties System

Tier	Minimum CMP per Violation	Maximum CMP per Violation	Maximum CMP per Calendar Year
No Knowledge	$100	$50,000	$25,000
Reasonable Cause	$1,000	$50,000	$100,000
Willful Neglect-Corrected	$10,000	$50,000	$250,000
Willful Neglect—Not Corrected	$50,000 per violation	NA	$1,500,000

The penalties will be adjusted for inflation.

Takeaway: Labs best take heed of the new penalty rules, especially considering that 2018 was a record year for HIPAA enforcements, with HHS collecting an all-time high of $28.7 million in penalties from HIPAA-covered entities and their business associates. The good news is that in the future, HIPAA penalties should be much less robotic and labs will, rightly, earn consideration for the efforts they make to implement systems to ensure the privacy and security of PHI and prevent HIPAA violations.