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Enforcement Trends: Feds Take Down $2.1 Billion Medicare Genetic Test Fraud Scheme

You know that a branch of lab testing has gone from fad to mainstream when it becomes the subject of a major federal enforcement takedown. Accordingly, the newly announced breakup of a $2.1 billion genetic billing fraud scam, one of the largest Medicare frauds ever undertaken, signifies that genetic testing has officially arrived.

Operation Double Helix

Known as Operation Double Helix, this landmark investigation and prosecution was a joint HHS, DOJ and FBI crackdown carried out in five federal districts against 35 defendants associated with genetic testing labs (CGx) and telemedicine companies, including doctors, CFOs and CEOs that allegedly "capitalized on the fears of elderly Americans to induce them to sign up for unnecessary or non-existent cancer screening tests," according to one of the U.S. Attorneys involved.

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Focus On: HIPAA Enforcement Takes a Dramatic New Direction

Historically, HIPAA enforcement has focused predominantly on the failure of covered entities, including labs, to keep protected health information (PHI) private and secure; but now the scope is broadening to encompass keeping PHI too private and too secure. Last month, the HHS Office for Civil Rights (OCR), the agency that enforces HIPAA rules, broke new ground by fining a Florida hospital for failing to provide access to PHI to the individual it relates to. Here's a look at the case and what it portends about the new direction in HIPAA enforcement.

The HIPAA Right of Access

When you hear the term "HIPAA Privacy Rule," the first thing likely to jump into your mind is the obligation to keep PHI

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Old Wine in New Bottles

While the alleged kickback scheme follows a familiar pattern of paying doctors for referrals of Medicare patients for lab tests, it feels model and emblematic of the times to the extent it brings together:

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

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

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

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

In stage three, CGx labs in on the scam performed the prescribed tests and billed them to Medicare to the tune of $1.7 billion in total. When Medicare paid the bill, typically in the $10,000 to $18,000 range, the testing lab, ordering doctor and telemarketing firm that recruited the beneficiary split the money.

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

Takeaway: Operation Double Helix is the latest and most obvious indication that genetic testing fraud has become a central focus of federal enforcement. On June 3, 2019, the OIG issued a genetic testing fraud alert warning beneficiaries of exactly the kinds of scams perpetrated in

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Double Helix. See National Intelligence Report (NIR), July 15, 2019. There has also been a series of individual and non-coordinated enforcement actions against labs for genetic testing fraud. (To find out more about the crackdown and how to protect your lab, see G2 Blog.)

SCORECARD:

Lab Defendants Charged in Operation Double Helix Genetic Testing Takedown

Defendant	Role	Alleged Violations
Khalid Satary	Owner of CGx labs in GA, OK, LA	Paid telemarketers and doctors kickbacks for ordering $547+ million in medically unnecessary genetic tests from his labs
Kevin Hanley	CFO, Acadian Diagnostic Laboratories (LA)	Paid telemarketers and doctors kickbacks for ordering $240+ million in medically unnecessary genetic tests from Acadian and other CGx labs
Mark Allen	Owner of telemarketing firms	Paid telemarketers and doctors kickbacks for ordering $240+ million in medically unnecessary genetic tests from Acadian and other CGx labs
Edward B. Kostishion, Kacey C. Plaisance, Jeremy Richey	Operators of Ark Laboratory Network LLC (Ark)	Took bribes from labs in exchange for delivering DNA samples and orders for genetic tests and used sham hourly invoices to conceal arrangement
Kyle D. Mclean	Operator of Privy Health, Inc.	Partnered with another company to acquire DNA samples and Medicare information from hundreds of patients, including via offering $75 gift cards to patients, all without the involvement of a treating health care professional
Matthew S. Ellis, MD	Physician	Served as Ark and Privy Health's ordering physician who authorized $4.6 million in genetic testing for hundreds of patients he never saw, examined or treated

Innovation & Data: Quest-hc 1 System Leverages Lab Data to Help Providers Monitor Test Utilization

Getting Medicare and private insurers to pay for lab tests is as challenging as it's ever been. It's not just about reimbursement. Payors have become fanatically dedicated to weeding out lab testing overutilization. While this puts the squeeze on labs, it also creates opportunity to the extent that the source of the most direct and useful data for identifying and preventing lab test overutilization and underutilization are the labs and ordering providers themselves.

The Quest Lab Stewardship Service

The opportunity for labs to leverage their own test data for utilization monitoring has not been lost on Quest Diagnostics, which recently announced that it was partnering with healthcare data analysis firm to offer an innovative new service to help health systems control and track test ordering. Quest Lab Stewardship is designed to integrate with the electronic medical record to guide doctors through the test ordering process so they can be sure they're ordering the right tests and in the right amounts to ensure proper treatment and reimbursement. The system also has the capabilities to create a systemwide set of tests and utilize testing trends across the entire organization.

That's a big deal because health systems typically do a poor job of how much their lab testing varies across the network, explains hc1 CEO, **Brad Bostic**. "They usually have a multitude of test compendia in various hospitals that have been acquired and consolidated—getting a standard one is almost impossible." This variation in testing patterns can lead to higher costs and poorer outcomes.

How It Works

On the front end, the Quest Lab Stewardship system displays the tests that a patient most likely needs based on customized parameters which also make lower-value or less-proven tests harder to order. It alerts physicians if tests are ordered twice and directs them to testing results. The system can also be used to monitor ordering patterns, both organizationally and by individual doctors.

In addition to selling the new service, Quest is using to improve client relations by making it available for free to its reference lab customers. "There are opportunities to drive out overutilization and underutilization, but it's really about driving clinical value," explains **David Freeman**, general manager of information ventures at Quest. "It is about giving clinical lab directors the tools they need to help them figure out where the problems are" and how they can be solved.

New Laws: The 4 Things You Need to Know about the New CMS Medicare Exclusions Rule

The new Final Rule CMS issued in September purporting to strengthen the agency's exclusion powers is something all labs participating in Medicare, Medicaid, CHAMPUS and other federal health insurance programs (which we'll refer to collectively as "Medicare") need to be concerned about. In a nutshell, CMS is seeking to move from a reactive to proactive approach designed to stop fraud before it happens by keeping unscrupulous providers out. To accomplish this objective, the final rule gives CMS authority to revoke the Medicare enrollment of healthcare providers or suppliers that are currently or have in the last five years been affiliated with targeted "bad actors" currently, or within the last five years. These are some of the most significant new Medicare program rules, says **Deborah Samenow**, Counsel at Baker, Donelson, Bearman, Caldwell & Berkowitz, PC. And they may also have unintended consequences that affect your lab.

The Final Rule

The Final Rule, aka the Program Integrity Enhancements to the Provider Enrollment Process, takes effect on Nov. 4, 2019. "For too many years, we have played an expensive and inefficient game of 'whack-a-mole' with criminals—going after them one at a time—as they steal from our programs," according to a press release quoting CMS Administrator **Seema Verma**. "These fraudsters temporarily disappear into complex, hard-to-track webs of criminal entities, and then re-emerge under different corporate names. These criminals engage in the same behaviors again and again."

The 4 Things You Need to Know About the New Rule

Behind the rhetoric are some potentially significant consequences that could jeopardize the enrollment status of your lab and/or the individuals affiliated with it. Here are the four key things you need to know.

1. How the New Affiliations Rule Works

A key part of the Final Rule is the new "affiliations" provision that allows CMS to bar individuals and organizations that affiliate with those who pose an "undue risk" of committing fraud, waste or abuse based on their relationships with other previously sanctioned entities. While it may sound like legalese, this language is significant because it means that you can be held liable not simply for what your principals, employees and business affiliates do at your lab but what they did during the lookback period, i.e., the five years before they came to your organization.

Example: Your lab can have its Medicare enrollment revoked if one of its owners was an owner or managing employee at another lab that had its

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enrollment revoked within the past five years.

The other scary part is how broadly the Final Rule defines "affiliates," cautions Samenow, which includes individuals and entities that:

- Have a direct or indirect ownership of 5% or more in another organization;
- A general or limited partnership interest, regardless of the percentage;
- An interest in which an individual or entity "exercises operational or managerial control over, or directly conducts" the daily operations of another organization "either under direct contract or through some other arrangement"
- Act as an officer or director of a corporation; or
- Have any reassignment relationship with the organization.

2. The New Disclosure Requirements

The Final Rule requires providers to disclose any direct or indirect affiliation they've had within the previous five years with a provider or supplier that has:

- Uncollected debt;
- Been or is subject to a payment suspension under Medicare;
- Been excluded from Medicare; or
- Had its Medicare billing privileges denied or revoked

"The Final Rule seems to indicate that providers and suppliers must report any affiliations within the past five years where such affiliated individuals or entities had any disclosable events ever in their history."

Deborah Samenow, Counsel, Baker, Donelson

Somewhat problematic, notes Samenow, is that there is no specified period of lookback for these disclosable events once a provider or a supplier has identified an "affiliation." The Final Rule, she says, seems to indicate that providers and suppliers must report any affiliations within the past five years where such affiliated individuals or entities had any disclosable events ever in their history. For example, you'd have to report any affiliated individual or entity that has ever had uncollected debt.

3. The New Grounds for Revocation

The Final Rule also gives CMS power to revoke or deny Medicare participation for providers or suppliers who:

- Try to come back into the Medicare program under a different name after they've had their enrollment revoked or denied;
- Bill for services or items from noncompliant locations;
- Exhibit a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services or drugs; or

- Owe CMS money from an overpayment referred to the US Treasury Department.

4. The New Penalties

Other new punitive powers given to CMS under the Final Rule is the authority to:

- Prevent a provider or supplier that's found to have submitted false or misleading information in its initial enrollment application from enrolling in the program for up to 3 years;
- Prevent fraudulent or otherwise problematic providers from re-entering Medicare ever again;
- Ban revoked providers and suppliers from re-entering Medicare for up to 10 years, as opposed to three years under previous rules; and
- Ban providers and suppliers that have had their Medicare enrollment revoked twice from re-entering the program for up to 20 years.

Takeaway: Once the Final Rule takes effect on Nov. 4, labs will have to closely screen their officers, directors and business affiliates to verify that they haven't been excluded from or barred entry into Medicare or other federal health insurance program within the past five years or risk losing their own enrollment status.

Global Markets: IVD Makers Fear New EU Rules Will Create Bottlenecks in Europe

If your lab organization does business in Europe or with European firms, you need to be on top of what's happening with the new European Union (EU) MedTech rules. While the new standardized device requirements are slated to take effect next May, the diagnostic rules, which are contained in the In Vitro Diagnostic Medical Devices Regulation (IVDR 2017/746), officially go into effect two years later on May 26, 2022. Here's an overview and quick briefing.

How Products Get Admitted into European Markets

To understand IVDR 2017/746, you need to know a little bit about the European Single Market, i.e., the mechanism designed to ensure free movement of goods, including medical devices, among the member states. (Those states include the 28 EU Member States (including the UK), Switzerland and the European Economic Area made up of Iceland, Liechtenstein and Norway.) "Free movement" basically means that a

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product allowed on the market in one Member State is also allowed in the markets of the other Member States. There are three basic required conditions for free movement (as described in the 2016 version of the 'Blue Guide' on the implementation of EU products rules):

Essential requirements for the products involved must be defined;

- Methods for demonstrating the products' compliance with free movement requirements must be established; and
- Mechanisms to supervise and control the actions of all Economic Operators and others involved in the manufacturing and distribution of the products must be created.

EU countries designate an organization called a "Notified Body" to assess whether products seeking entry into the country's market meet the necessary requirements. before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.

Regulation of Medical Devices

The EU defines IVDs or companion diagnostics as in vitro diagnostic tests that support the safe and effective use of a specific medical product, by identifying patients that are suitable or unsuitable for treatment. They're a subset of the broader medical device category and can include clinical tests that analyze samples from the human body to detect disease.

The 1998 In Vitro Medical Devices Directive (IVDD) 98/79/EC) (the 1998 Directive) created the Single Market for IVDs in Europe. It defines Essential Requirements, establishes harmonized standards to demonstrate conformity to the Essential Requirements, defines

conformity assessment procedures, and facilitates the organization of Notified Body and Competent Authority oversight and market surveillance. However, the 1998 Directive doesn't regulate all new technical and medical developments.

Overview of IVDR 2017/746

In September 2012, the European Commission published the initial proposals for the regulations for medical devices and IVDs. In April 2014, the European Parliament came up with a total of 347 amendments for the proposed MDR and 254 amendments for the proposed IVDR that would become IVDR 2017/746. The European Council responded in September 2015 to the proposals adapted by Parliament. The differences between these versions were so significant that the European Commission decided to facilitate negotiations between European Parliament and Council, the so-called "Trilogues." The Trilogues resulted in a compromise text in June 2016. By late 2016, these texts had been translated into all European languages and (legal) errors and inconsistencies were corrected. The Regulations were formally published in the Official Journal of the European Union on 5 May 2017.

Perhaps the biggest concern is that the need for Notified Body approval will create big bottlenecks in getting products to the EU market. The problem is that it's taking so long to designate, on average 18 months, and somewhat less if the organization doesn't have many nonconformities to correct. Thus far, only a total of four Notified Bodies have been designated, and under IVDR 2017/746 not one has received that status.

The IVDR 2017/746 Changes

One of the biggest practical impacts of the new IVDR 2017/746 standardized rules will be the new model for product approval. IVDR 2017/746 departs from the current pre-approval stage to a life-cycle model, similar to the one followed by the US Food and Drug Administration and many international standards. The life-cycle approach is illustrated by the incorporation of European guidance (MEDDEVs) into the regulation. Some of concepts that were not previously applicable to IVDs include:

- Borderline and Classification issues;
- Authorized Representation;
- Performance Evaluation;
- Vigilance; and
- Post-Market Performance Follow-Up.

Currently, the European IVD industry is an €11 billion market with about 3,000 companies and 40,000 products. Under the new rules, far

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more IVDs will have to undergo pre- and post-market review. Under current1998 Directive rules, approximately 90% of the IVD industry can self-certify and only 10% require certification from a Notified Body. Once the new rules are phased in, however, those percentages are expected to flip with 90% requiring Notified Body certification.

Practical Impact of the New Rules

The medical device industry faces significant challenges in adapting to the new requirements. Perhaps the biggest concern is that the need for Notified Body approval will create big bottlenecks in getting products to the EU market. The problem is that it's taking so long to designate, on average 18 months, and somewhat less if the organization doesn't have many nonconformities to correct. Thus far, only a total of four Notified Bodies have been designated, and under IVDR 2017/746 not one has received that status.

The European Commission has suggested the first Notified Body designated under the IVDR should come soon. Even then, some point out there will still be delays while the Notified Body hires staff and trains them to be able to be competent enough to handle the technical aspects of IVDs. The slow pace of designating Notified Bodies creates problems for IVD manufacturers trying to create a strategy to implement the new rules.

MedTech Europe estimates that if just 11 notified bodies got IVDR status, each organization would need to process 3,200 IVDs. If all 22 Notified Bodies apply for designation each Notified Body would, on average, need to assess at least 1,600 IVDs each.

Takeaway: The Commission has given IVD manufacturers five years to transition to the new regulation. But there is nothing built into the IVDR that explains what happens if Notified Bodies aren't available in time or don't exist for particular segments of the industry. In the meantime, experts are recommending companies to start looking for a Notified Body now and becoming an existing client. Get all necessary requirements in order, and ready to apply for IVDR certification once the Notified Body gets designation.

HIPAA Enforcement Takes a Dramatic New Direction, *from page 1*

secure and refrain from disclosing it to third parties without appropriate authorization. But there's another lesser known part of the (Rule 45 C.F.R. § 164.524(a)) that requires labs to give individuals access to their own PHI. Specifically, individuals have the right to see, amend and get copies of the PHI you keep about them in one or more "designated record sets." Upon receiving a request, the lab has 30 days to provide access to the information, unless it can cite a legal ground for denying the request.

The so-called right of access applies to all forms of PHI, including lab test results, billing information and other medical records except:

- Psychotherapy notes; and
- Information compiled in reasonable anticipation of, or for use in a civil, criminal or administrative action or proceeding.

There are also rules setting out the valid grounds for denying an access request, (e.g., you don't have to let individuals amend their PHI if you determine that it's accurate and complete) as well as the timing and format of disclosure and the fees you can charge.

The OCR Right of Access Initiative

Over the years, right of access has generated roughly one in three of all HIPAA complaints to the OCR. However, all of the enforcement litigation and most of the Phase 2 compliance audits have targeted privacy and security breaches.

Earlier this year, the OCR signaled a significant policy change by announcing the Right of Access Initiative promising to vigorously enforce the rights of individuals to receive copies of their medical records promptly and without being overcharged. "Providing patients with their health information not only lowers costs and leads to better health outcomes, it's the law," noted OCR Director Roger Severino. "We aim to hold the health care industry accountable for ignoring peoples' rights to access their medical records and those of their kids."

The Bayfront Hospital Settlement

Apparently, the OCR wasn't kidding. On Sept. 9, 2019, the OCR announced that Bayfront Health St. Petersburg, a Level II trauma and tertiary care center licensed as a 480-bed hospital with over 550 affiliated physicians, agreed to pay $85,000 and adopt a corrective action plan to settle charges for denying a mother timely access to her unborn child's PHI, making it the first ever monetary settlement of a HIPAA right of access claim. In addition to the fine, Bayfront also had to sign a corrective action plan promising to "develop, maintain, and revise, as necessary, its written access policies and procedures" to ensure compliance with HIPAA right of access requirements.

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The case itself was fairly routine. It began in October 2017 when the mom sent Bayshore a timely written request for access for the fetal heart monitor records from her delivery. We can't find the records, Bayfront replied. The mom then went to an attorney and filed a complaint with the OCR, which initiated an investigation. In August 2018, Bayshore finally produced the records. But the HIPAA 30-day deadline had long passed by then.

Takeaway: A New Era in HIPAA Enforcement

Denying individuals access to their PHI has always been illegal; the difference is that now it can result in fines and other penalties. The Bayfront case is only the first enforcement action under the Right of Access Initiative. Expect many more to follow in the months and years ahead. ***Bottom Line:*** *We have entered a new era in HIPAA enforcement, one that makes it imperative for labs to respect patients' rights to see, copy and amend their lab records without being overcharged for doing so.*

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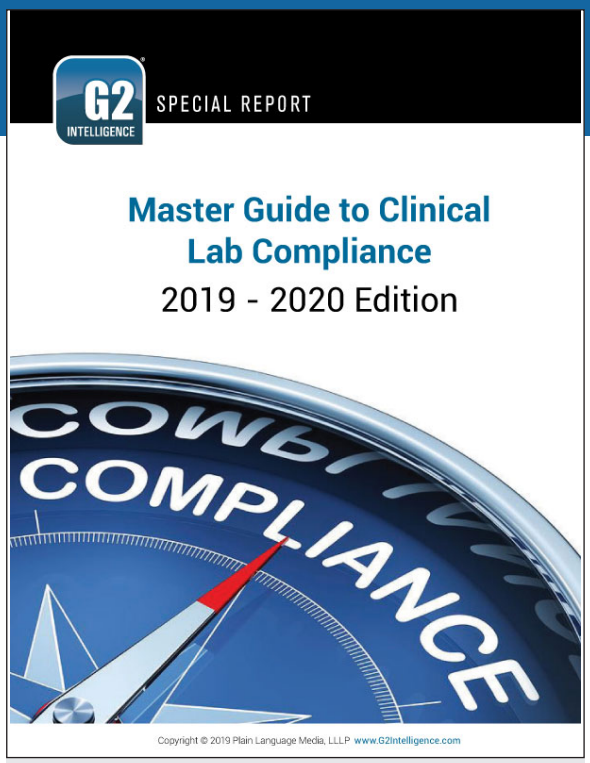

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