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Covering Government Policy For Diagnostic Testing & Related Medical Services

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Enforcement Trends: After 2017 Decline, False Claims Act Healthcare Recoveries Bounce Back

Although the False Claims Act (FCA) remains a federal enforcement cash cow, the growth rate has fallen off in recent years, at least in the healthcare sector. But that short-term trend could be in reversal. Thus, after last year's surprising decline, FCA recoveries against healthcare providers rebounded in 2018 to reach $2.513 billion, which exceeded not only the $2.184 billion total recoveries in 2017 but also the 10-year average of $2.3 billion. Of course, what never changes is the industry's perennial position as the leading source of FCA recoveries.

2018 By the Numbers

Here are the key numbers from the year in 2018 FCA recoveries, as reported by the DOJ at year's end:

- **$2.8 billion:** Total FCA recoveries in FY 2018;
- **$2.5 billion:** Total recoveries against healthcare providers in FY 2018 (not including state Medicaid);

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CLIA: CMS Proposes 20% Fee Increase—and Further Increases Could Follow

As if Year 2 of PAMA lab fees wasn't enough, CMS dished out another dose of agita to the lab industry: CLIA fees will be going up 20%, effective this year.

Background

For those of you who are new to the industry, the CLIA statute, aka *Clinical Laboratory Improvement Amendments of 1998*, requires labs to obtain certification from CMS to legally perform tests on human specimens for purposes of providing information for the diagnosis, prevention or treatment or assessment of health. CLIA fees are paid by labs seeking certification and used to defray CLIA program expenses.

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After 2017 Decline, False Claims Act Healthcare Recoveries Bounce Back, *from page 1*

- **$37.8 billion:** Total FCA recoveries between 2009-2018;
- **$3.7 billion:** Average annual FCA recoveries for three-year period 2016-2018;
- **$22.7 billion:** Total FCA recoveries from healthcare providers between 2009-2018;
- **$2.3 billion:** Average annual FCA recoveries from healthcare providers between 2009-2018;
- **645:** Total *qui tam* (whistleblower) lawsuits filed in FY 2018, an average of 12.4 cases per week;
- **$2.1 billion:** Total recoveries in *qui tam* lawsuits in FY 2018;
- **$301 million:** Total recoveries paid to whistleblowers in FY 2018.

Top 5 FCA Healthcare Recoveries

Labs and lab services did not figure directly in any of the five largest civil recoveries in the healthcare industry during the year, which included cases against:

1. **AmerisourceBergen Corporation and its subsidiaries:** $625 million to resolve allegations of seeking to circumvent important safeguards intended to preserve the integrity of the nation's drug supply and profit from the repackaging of certain drugs supplied to cancer-stricken patients;
2. **HealthCare Partners Holdings LLC (HCP), dba DaVita Medical Holdings LLC:** $270 million to settle charges of providing inaccurate information that caused Medicare Advantage Organizations (MAOs) to receive inflated Medicare payments;
3. **Health Management Associations (HMA):** $216 million to resolve allegations of: i. Billing government healthcare programs for more costly inpatient services that should have been billed as observation or outpatient services; ii. Paying illegal remuneration to physicians for patient referrals to HMA hospitals; and iii. Inflating claims for emergency department facility fees;
4. **United Therapeutics Corporation:** $210 million to settle allegations of using a foundation as an illegal conduit to pay the co-pay obligations of thousands of Medicare patients taking its PAH drug; and
5. **William Beaumont Hospital:** $84.5 million to resolve allegations of improper relationships with eight referring physicians intended to induce patient referrals.

Lab Enforcement Trends

Continuing recent trends, the DOJ targeted individuals and not just faceless entities. Of the individuals the DOJ cited as being held personally liable for alleged false claims in 2018, several involved lab testing, including:

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- Three individuals who entered into a $114 million settlement for their role in the notorious kickback scheme involving blood testing labs Health Diagnostic Laboratory (HDL) and Singulex Inc. in which physicians were paid bribes disguised as "handling fees" of between $10 and $17 for each patient they referred; and
- Dr. Michael Frey, a pain management specialist and one of two principal owners of Advanced Pain Management Specialists P.A. in Fort Myers, Florida, who agreed to pay $2.8 million to resolve allegations that he violated the FCA by receiving illegal kickbacks and ordering medically unnecessary lab tests.

FCA Recoveries in *Qui Tam* Cases against Healthcare Providers

Since 2009 (in billions of dollars)

Year	*Qui Tam* Recovery against Healthcare Providers	Total Recovery against Healthcare Providers
2009	$1.398	$1.636
2010	$1.972	$2.519
2011	$2.271	$2.449
2012	$2.548	$3.105
2013	$2.673	$2.734
2014	$2.344	$2.432
2015	$1.966	$2.127
2016	$2.627	$2.724
2017	$2.151	$2.184
2018	$1.945	$2.513
Total	**$21.895**	**$24.423**

Source: U.S. Department of Justice

Takeaway: The DOJ's reporting of FY 2018 fraud recoveries show that large scale and individual enforcement efforts continue—and that lab testing remains a major target for enforcement agencies.

New Law: EKRA Makes Drug Addiction & Rehab Labs Potential Targets for Federal Prosecution

Recent federal legislation addressing the opioid crisis may have unintended consequences on the lab industry. The idea was to allow the feds to prosecute a certain kind of abuse banned by the Anti-Kickback Statute (AKS) even when it doesn't involve a government health program. The new prosecution authority was intended to apply just to private-pay arrangements involving drug addiction treatment and rehabilitation services. But because of the way it was drafted, the new federal prosecutorial power applies to all private-pay arrangements.

What Happened?

On Oct. 24, 2018, the President signed the Substance Use-Disorder Prevention

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that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the "SUPPORT Act") consolidating several different opioid-related bills. One of those bills, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), EKRA creates criminal penalties for "patient brokering," i.e., an arrangement where 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. The sober home or treatment facility then bills the insurance company for treatment services, which often are of substandard quality or never provided at all.

Because the AKS covers just government programs like Medicare and Medicaid, it can't be used to prosecute brokering arrangements involving patients with commercial or private-pay insurance. EKRA was intended to close that gap. Specifically, 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.

EKRA Exceptions

The EKRA ban is subject to exceptions, including for:

- Certain disclosed discounts under a healthcare benefit program;
- Certain payments to bona fide employees and independent contractors (although there are several provisos to this rule and it doesn't mirror a similar exception in AKS);
- Payments for services that meet the AKS safe harbor for personal services and management contracts;
- Certain coinsurance and co-payment waivers and discounts;
- Certain federally qualified health center arrangements that meet the AKS exception; and
- Remuneration made pursuant to certain arrangements that HHS deems necessary.

The Law of Unintended Consequences

Letting the feds prosecute kickbacks involving private payers is a big departure and, arguably, an encroachment on the prosecutorial powers of the states which have their own kickback laws. So, the EKRA exception was supposed to be a narrow measure to deal with the opioid crisis. The problem is that EKRA's language is so broad that it permits prosecution of any lab or non-hospital provider who provides addiction treatment or recovery services, even if the referral in question does not involve addiction treatment and recovery services.

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Is This Some Kind of a Bad Joke?

It appears that this hair-raising consequence was unintended. If so, prosecutors may decline to use their new powers in cases not involving addiction and recovery. Better yet, Congress may go back and amend the statute so that it's more narrowly tailored to addiction treatment or recovery services referrals.

Takeaway: How to Protect Yourself

The problem is that it's unclear when that will happen—or even whether it will happen at all. So, for now at least, if your lab provides these services, you may now be subject to not just state but also federal prosecution for patient brokerage arrangements even if they don't involve addiction treatment and recovery services. The good news is that because such arrangements are currently illegal under state laws, your current arrangements and relationships are probably already compliant. Still, the overlap between the AKS and state kickback laws isn't 100%. Result: Unless and until the EKRA rule is modified or neutered by the Justice Department, you need to vet all your current provider relationships and arrangements for patient brokering risks.

Physician-Owned Labs May Be Especially Vulnerable

Last but not least, the new laws create a compliance risk for physician-owned labs that avoided AKS by structuring referrals so that only non-federally and non-state covered patients are referred. Such safeguards may no longer be enough, and you may need to restructure your arrangements to ensure compliance with the new rules. Given the broad scope of EKRA physician-owned labs need to review and potentially restructure their business arrangements to avoid violating the statute.

Industry Buzz: When It Comes to Obamacare, Uncertainty Is the Only Certainty

Last month, a U.S. District Court Judge ruled that the *Affordable Care Act*, aka Obamacare, is unconstitutional—not just the individual mandate but the whole bloody law. But if you were expecting closure, forget it. The legal battle is just beginning and appears inevitably headed to the Supreme Court. Here's a quick rundown of where things stand and where they're likely to go.

Texas v. United States

Wait a minute. Didn't the Supreme Court already say that Obamacare *is* constitutional? In fact, it did, about six years ago in a case called *NFIB v. Sebelius*. But the ruling was based on the mandate coupled with the penalty for not having health insurance, which the Court found to be a lawful exercise of the U.S. Congress's constitutional taxing powers.

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The problem is that the penalty is now gone. Upon taking control of Congress, the Republicans cut the penalty amount to $0, effective in 2019. And with the penalty eliminated, the *Sebelius* justification of Obamacare as a constitutional federal tax no longer pertains. At least that's what the Republic governors bringing the new case contend.

And the judge in that new case, *Texas v. United States*, agreed. But that's not all. Reasoning that the mandate can't be severed from the rest of the law, the Judge Reed O'Connor found the entire Obamacare law unconstitutional.

The Stay: Repeal Put on Ice

Shocking as it was, the ruling was just the opening salvo. On Dec. 30, Judge O'Connor issued an order staying his own ruling. **Translation:** The ruling can't take effect unless and until the federal Appeals Court (or perhaps the Supreme Court) upholds it.

But to the extent the stay represents a capitulation, Judge O'Connor didn't go quietly, issuing a 30-page opinion (as opposed to the one or two pages stay rulings normally run) defending his opinion and the right of Republican states to bring the case.

So, Now What?

Next up is an appeal with the Court of Appeal for the Fifth Circuit, among the country's most conservative. But even if the Fifth Circuit upholds the ruling, the case will go to the U.S. Supreme Court. All of this will take at least a year. And in that period, Obamacare will remain valid law.

After that, it's anybody's guess. Even though the Court is veering right, this case raises important constitutional issues that go beyond partisan politics, such as the question of whether a group of states can bring a case challenging the constitutionality of a federal law they don't like.

If the Supreme Court does affirm the ruling, even Republicans admit that all heck is going to break loose in the insurance markets. The Trump Administration has come out in support of the ruling and is unlikely to intervene in the appeal on the side of the Democrats. However, Obamacare repeal—or merely the realistic threat of it—will spur Congress to come up with a substitute system. The substitute will have to be created on an urgent basis and might, gasp, require bipartisan support.

Stay tuned. Things are about to get interesting.

Industry Buzz: New Study Finds Lab Automation Market Poised for Continued Growth, Focus on Genomics Solutions

The lab automation market is expected to reach $5.20 billion by 2022 from an estimated $4.06 billion in 2017, at a CAGR rate of 5.1%, according to leading B2B research company MarketsandMarkets.

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The Study

Objective: The objective of the new report: Analyze lab automation with the aim of:

- Defining, describing and forecasting the lab automation market by equipment and software, application, end user and region; and
- Providing detailed information on the major factors influencing the growth of the market (drivers, restraints, opportunities and challenges).

Methodology: The report analyzes lab automation, by equipment and software, in six primary categories:

- Automated workstations;
- Off-the-shelf automated workcells;
- Robotic systems;
- Automated storage & retrieval systems;
- Other equipment; and
- Software.

It also looks at the lab automation market by application, including:

- Drug discovery;
- Clinical diagnostics;
- Genomics solutions;
- Proteomics solutions;
- Microbiology; and
- Other applications.

Findings: Largest Market Share, 2017

The automated workstations segment currently accounts for the largest share of the lab automation market, according to MarketsandMarkets. The firm cites high demand for automation in liquid handling as the key factor driving market growth in this segment. It notes that automated workstations offer advantages such as enhanced accuracy, and reduced time and cost.

Findings: Projected Growth, 2022

Based on applications, the genomics solutions segment is expected to grow at the highest CAGR during the forecast period. The firm finds that use of automation is on the rise in genomics for high-throughput requirements, providing greater reproducibility and throughput as compared to manual methods.

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Labs IN COURT

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

Wisconsin Health System Settles Stark Claims for $12 Million

Case: In a case that began as a whistleblower suit, a company affiliated with Advocate Aurora Health, Inc. has agreed to pay $12 million to settle claims of violating the Stark Law. The US and State of Wisconsin cited the company for improper relationships with a pair of physicians between 2008 and 2012, including providing compensation:

- At above fair market levels;
- That took into account the volume of anticipated referrals; and
- That covered unidentifiable services.

Significance: The case is a good illustration of how whistleblower lawsuits become a lingering pain in the side that may be hard to settle. Although the relator who brought the original suit will get a share of the $12 million recovery, the government intervention covered only some of the original claims. As a result, the settlement doesn't end the litigation and the whistleblower suit will continue as a separate case covering the residual claims. The good news for Aurora is that:

- The government won't be involved in the subsequent case; and
- The settlement will have no bearing on its liability in that case.

HIPAA ePHI Violation Costs Colorado Hospital $111,400

Case: This case began when the Office of Civil Rights (OCR) received a complaint contending that an ex-employee of Pagosa Springs Medical Center (PSMC) still had remote access to the critical access hospital's web-based scheduling calendar containing electronic PHI of 557 patients. OCR investigators confirmed the allegation and found that the ex-employee had accessed the calendar on at least 2 occasions since leaving PSMC. To make matters worse, PSMC got the calendar from Google without having it sign a business associate agreement (BAA) (at the time, Google Calendar wasn't a HIPAA compliant" service the way it is today). In addition to the $111,400 fine, the settlement requires PSMC to sign an onerous 2-year Corrective Action Plan with OCR agreeing to overhaul its information security management, BAA and employee training systems.

Significance: The moral of this case is to ensure that your lab:

- Immediately terminates employees' access to ePHI when they leave your company or remain but no longer require access to do their jobs; and
- Enters into a BAA with vendors before disclosing your ePHI to them.

Despite Vigorous Denial, Molecular Lab Pays $1.8 Million to Settle Fraud Charges

Case: The feds claim that Molecular Testing Labs, a toxicology and genetics lab in Washington State, paid local labs in exchange for Medicare and Tricare referrals; it then turned what had been an *Anti-Kickback Statute* offense into a *False Claims Act* violation by billing for the tests it provided as a result of those ill-gotten referrals. While unshakably adamant about its innocence, the lab recognized that discretion is

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the better part of valor and agreed to pay out up to $1.8 million to settle.

Significance: While credible, Molecular's vigorous denial of wrongdoing is a potent reminder of the Hobson's choice providers face when charged with fraud violations: invest a fortune in time, effort and legal fees to resist or pay a substantial settlement amount to make the situation go away. Citing the hundreds of thousands it had already racked up, a written statement from Molecular's chief compliance officer said that, like many healthcare providers do, it entered into the settlement so it could "stop spending our valuable resources on the case.

Industry Trends: The Worker Shortage and Your Lab

If you're having trouble finding employees, all you have to do is look at the numbers to understand the problem.

The national unemployment rate stands at 3.7%—and in some states it's even lower. In fact, in nine states, it's below 3%. Against this backdrop, there are 7.1 million job openings.

Where are the workers to fill these jobs? Most of them are already employed.

Other Factors

Meanwhile, the U.S. Bureau of Labor Statistics (BLS) indicates that medical and diagnostic laboratories is one of the fastest growing industries, with a projected growth rate of 27.4% between 2016 and 2026.

Where will the workers come from, to fuel and support this growth?

If you're thinking from other countries, you may want to think again. The number of undocumented immigrants has been steadily declining since 2007, according to the Pew Research Center.

At the same time, the Trump administration has attempted to ban legal immigrants from certain countries and reduce the number of refugees allowed to enter the United States. While some of these actions have been challenged in court, there have been short-term impacts on the labor market. Longer-term impacts depend on legal outcomes, as well as future administration efforts in this area.

Finding Solutions

So, what can you do to counteract these issues that are beyond your control?

Focus on areas where you can have an impact. These include:

- **Salary.** Make sure your salaries are competitive for your industry, and that they are in line with what others are paying in your region. The salary tool at job site Indeed and Salary Wizard at Salary.com can help.
- **Benefits.** If you haven't done so recently, take a look at your benefits package. How does it compare to what your competition offers? If, for

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example, other employers provide fully-paid medical and dental and your lab doesn't, they have an advantage. Similarly, number of paid vacation days matter to job seekers.

Where can you find this information? Search job postings for the same or similar lab positions. Also look at job ads for regional employers outside the industry.

- **Culture.** Employees sometimes leave companies, but more often they leave bosses. With this in mind, take an honest look at your workplace culture. Is management supportive? Do employees feel valued? Is there a sense of camaraderie and team spirit? How would staff members rate working at your lab? If you have no idea, it's probably time to find out. Employee surveys can prove eye-opening.

  This is important because employee referral remains a top source of new hires.

- **Retention.** In addition to helping you attract new employees, attention to salary, benefits, and culture will help you keep the staff you have.

  Employee recruitment and employee recruitment go hand in hand – or at least they should.

Yes, in a tight labor market, many factors are beyond your control. However, you have more control than you likely realize.

Still not convinced? Here's another noteworthy statistic: 82% of workers are open to a new job, according to Jobvite's 2018 Job Seeker Nation Study.

CLIA: CMS Proposes 20% Fee Increase—and Further Increases Could Follow, *from page 1*

Why Now?

The 2019 increase, the first since 1998, is made necessary by the simple fact that current fees aren't enough to cover program costs. According to CMS, "the current fee schedule is based on assumptions about program operations and workload made in 1992." The agency claims that the 20% fee increase is necessary to sustain and maintain the CLIA program through FY 2021.

Impact on Labs

The increase impacts certificate fees, which are billed on a two-year cycle. Certificate fees are based on 11 lab classification categories. Previous fees ranged from $150 (for low volume labs) to $7,940. The increase will take the range from between $180 to $9,528. The increase also applies to compliance determination fees and inspection fees for non-certified labs.

One-Time Adjustment or More to Follow?

CMS has positioned the 20% increase as a one-time adjustment to meet a budget shortfall. However, information shared at the *Federal Register -The*

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Daily Journal of the United States Government suggests that the shortfall has been ongoing. In fact, even though the 2017 shortfall is nearly double that of 2016, CMS comparative analysis for FYs 2012 through 2017 shows a shortfall for each of the last six years:

Shortfall by Year	
FY 2012	$4,982,484
FY 2013	$1,719,930
FY 2014	$7,250,677
FY 2015	$6,669,380
FY 2016	$4,735,970
FY 2017	$9,339,344

Bottom Line: Based on these numbers, the 20% increase, as substantial as it is, may not be enough and may ultimately turn out to be just the first of several adjustments necessary to put the CLIA program on sound financial footing.

'Got Comments?'

If you want to let CMS know what you think of the fee increase and changes to the calculation formula, you can comment electronically, via U.S. mail or by express/overnight carrier. Details for comment submissions are provided in the agency's notice. Deadline to comment: March 1.

Industry Buzz: New Study Finds Lab Automation Market Poised for Continued Growth, Focus on Genomics Solutions, *from page 7*

Source of Growth

North America currently commands the largest share of the global lab automation market. MarketsandMarkets cites:

- Increasing adoption of lab automation systems;
- Implementation of the Affordable Care Act (ACA) in 2010; and
- Economic stimulus programs such as increased funding for the National Institutes of Health (NIH) and National Science Foundation (NSF); and
- Increased R&D activities by biotechnology and pharmaceutical companies as drivers of market growth in North America.

Key Market Players

The firm also identifies companies serving as major players in the lab automation market, including:

- Tecan Group (Switzerland);

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- PerkinElmer (US);
- Danaher (Beckman Coulter & Molecular Devices) (US);
- Thermo Fisher (US);
- Agilent Technologies (US);
- Hamilton Robotics (US);
- Abbott Diagnostics (US);
- Eppendorf (Germany);
- QIAGEN (Netherlands);
- Roche Diagnostics (Switzerland); and
- Siemens Healthcare (Germany).

For more information, and the full report, visit the MarketsandMarkets website.

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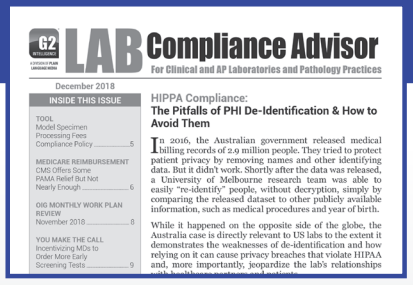
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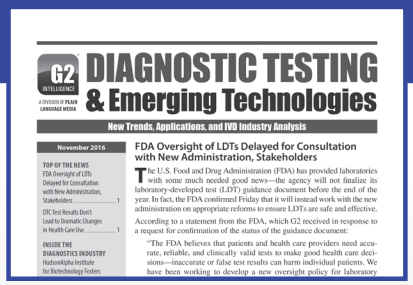
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