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LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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INSIDE THIS ISSUE

EKRA: More than a Year Out, Major Questions Remain Unresolved

One of the scariest new lab compliance laws in recent memory is the *Eliminating Kickbacks in Recovery Act of 2018* (EKRA). While laws banning remuneration in exchange for referrals is nothing new to labs, EKRA is much broader than the Anti-Kickback Statute (AKS) and Stark Law (Stark) that the industry has been dealing with for decades. The scary part is that EKRA is much broader than those laws. Worse, it may cast new doubt on the business, compensation and other arrangements that labs rely on to satisfy AKS and Stark. An arrangement that satisfies AKS and Stark, in other words, may not work for EKRA. The reason for emphasizing "may" and "may not" is that we simply don't know. The law is vague and lacking in implementing regulation. When it came out more than a year ago, the assumption was that the government would offer guidelines and clarification fairly

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Managing Lab Staff: Supervisor Liability for Subordinate Misconduct Under Civil Rights Law

Pop Quiz: Name five bad things that can happen if you fail to properly supervise your lab's testing staff.

Chances are, your response included testing inaccuracy leading to patient endangerment, CLIA citations, medical malpractice liability and termination of your job. But there's one more bad consequence that you might have to account for, especially if you work or perform testing for a public agency: potential money damages for violating a test subject's constitutional rights. A recent case illustrates how this can happen.

Chapter 1: A Decade of Undetected Testing Abuse

From 2003 to 2007, a chemist working at a lab run by the Massachusetts Dept. of Public Health (DPH) to do drug tests on samples submitted by law enforcement stole from the lab's supply of methamphetamine oils. When she got word that a supplies audit was planned in 2008, she added water to the depleted oils supply to cover up her theft. And it worked. The

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soon. Unfortunately, that hasn't yet happened. And there's no indication of when or even if it ever will.

What EKRA Is All About

EKRA is part of a larger piece of legislation enacted to combat the opioid crisis called the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* (SUPPORT Act) that took effect on Oct. 24, 2018. EKRA is the part of the SUPPORT Act that deals with labs and other providers. It imposes penalties of up to $200K and 10 years in prison for paying remuneration to induce or reward referrals to labs, clinical treatment facilities and recovery homes, including knowingly and willfully:

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

Of course, those things are also problematic under the AKS and Stark. The difference, though, is that unlike the current kickback laws, EKRA is an "all-payor" statute, i.e., it applies not just to Medicare, Medicaid and other government health programs but also to lab services paid for by *commercial insurers*. Luckily, many compliance-conscious labs already vet their private payor arrangements for potential kickback issues, notes Savannah, GA, health attorney **Adam Walters**. The more serious concern is that EKRA doesn't include the exceptions and safe harbors contained in the AKS and Stark laws to allow leeway for legitimate referral arrangements that may otherwise raise kickback concerns. Result: There's no way to be sure that arrangements structured to comply with AKS and Stark exceptions and safe harbors will also comply with EKRA.

3 Potentially Problematic Arrangements

Walters says that there are three kinds of commonly used lab arrangements that EKRA calls into particular concern.

1. Variable Compensation Tied to Referrals

Although it doesn't impose a blanket ban on commissions, EKRA does prohibit variable compensation paid by labs that's based on the value or volume of referrals generated, particularly commissions and bonuses to sales and marketers based on the number of patients referred, tests performed and/or payments the lab receives.

2. Leasing of Space in Physicians' Offices

While some states already prohibit this practice, Walters notes that both AKS and Stark create exceptions for labs to make legitimate arrangements to lease space in the offices of referring physicians. But EKRA doesn't

LCA

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include any such exceptions or safe harbors.

3. Accountable Care Organization (ACOs) Participation Agreements

Many labs have taken advantage of current federal waivers to AKS, Stark and the *Civil Monetary Penalties* law that allow labs to enter into participation agreements with ACOs. However, the federal waiver does not include EKRA, which casts doubt on the legality of existing lab ACO participation arrangements.

Takeaway

Many have suggested that EKRA was rushed into passage without full consideration of these kickback effects. But the corollary to that school of thought is that once the dust settled and the problems became apparent, the government would step in and fix the problem. Relief could come in the form of:

- *Regulatory guidance from the Department of Justice (DOJ) clarifying whether arrangements that meet AKS and/or Stark exceptions or safe harbors also comply with EKRA;*
- *New DOJ implementing regulations setting out EKRA exceptions and safe harbors for particular arrangements, presumably in coordination with current AKS and Stark rules; or*
- *Legislation that eliminates, clarifies or revises the EKRA kickback prohibitions.*

But nearly 16 months after EKRA took effect, none of these things have happened, despite calls for clarification from the American Clinical Laboratory Association (ACLA) and other lab industry groups. We know that the DOJ and Congress are aware of and presumably looking into the problems. But so far, nobody has made a move. "The DOJ seems to be waiting for Congress and vice-versa," suggests one expert.

In the meantime, the lab industry has no choice but to assume that EKRA does apply to all existing arrangements, including those structured for AKS or Stark, and review or restructure them accordingly.

Which Labs Does EKRA Cover?

Another unanswered question about EKRA is whether the kickback restrictions apply to all labs or just toxicology labs. The EKRA law's focus is on toxicology, drug treatment centers and sober homes; on the other hand, the language of the statute is so broad that it seems to cover all clinical labs, not just toxicology labs.

MANAGING LAB STAFF, *from page 1*

supervisor performing the audit noticed the sample's unusual appearance, but "surmised that the drug was just degrading."

After the audit, the chemist's drug use intensified, and so did her brazenness. In addition to stealing the lab's other drug standards, including amphetamine, phentermine, ketamine, cocaine, ecstasy, marijuana and LSD, she began siphoning off a portion of actual test samples. In late 2011, she was assigned a sample from an undercover cop who allegedly purchased the substance from a gentleman named Penate. After three rounds of testing, the chemist reported them positive for a controlled substance. Penate was then indicted, convicted and sentenced to five to seven years in state prison.

By mid-2012, the chemist actually began manufacturing crack cocaine in the lab for her personal use at work. But things were about to unravel. After the misconduct of another chemist came to light, the supervisor did another audit and detected that samples were depleted or missing altogether. Shortly thereafter, he found one of the chemist's crack manufacturing beakers with a white residue on it and confronted her. She denied any wrongdoing. But the resulting suspicion was confirmed a few weeks later when it was discovered that two of the cocaine samples assigned to the chemist were missing. In 2013, the chemist was terminated; a year later, she pled guilty to evidence tampering, larceny of controlled substances from a dispensary and unlawful possession of a Class B substance.

Chapter 2: The Innocent Victim

And what of poor Mr. Penate? From the very beginning, something seemed amiss about the testing. When the samples were returned to the officer who brought them to the lab, they no longer matched the descriptions on the evidence tags. Even stranger was the unexplained packet labeled "MOONWALK" improperly included among the materials returned. And when news of the chemist's termination and drug abuse came to light a few months later, Penate's attorneys tried to get the charges dismissed. But the judge reasoned that the chemist's misconduct happened after she tested the Penate sample and denied the motion.

It wasn't until May 2015 that the full extent of the chemist's wrongdoing was revealed. Penate moved for and got a new trial. In June 2017, his eviction was vacated and he was released from prison the very next day.

Chapter 3: Penate v. Lab Supervisor

And here's where our story morphs from anecdote into directly relevant legal analysis for lab managers. Two months after getting out of prison, Penate took legal action against those responsible for wronging him. The legal basis of the lawsuit: *The Civil Rights Act of 1871*, aka, 42 U.S.C. §1983, a federal statute that allows people to bring civil actions for money

damages against the government for civil rights violations. The case targeted not just the state police, attorney general and DPH but also the lab supervisor.

The key point: Supervisors of government agencies who allow their subordinates to violate a person's constitutional rights can be liable under §1983. Surely, the lab supervisor in this case was negligent for failing to detect what the chemist was up to. But mere negligence isn't enough. To establish "supervisory liability," the person must show that the supervisor would and should have known of the subordinate's conduct but for his/her "deliberate indifference" or "willful blindness."

The key question: Did the supervisor's failure to rein in the chemist rise to this level?

Answer: The federal court said no.

Explanation: Penate cited three things that should have put the supervisor on notice of what was taking place:

- The first supplies audit in 2008;
- The revelation of drug-related misconduct by chemists at another DPH lab; and
- The beaker incident.

But the court didn't buy it. The supervisor's failure to investigate these incidents, whether individually or collectively, didn't amount to "deliberate indifference." Hindsight is 20/20, and it's easy to overlook the extensive steps the chemist took to hide her drug abuse and cover up her theft. The chemist had a clean discipline record and there was no allegation that anybody at the lab knew that she was abusing drugs, much less that her abuse was causing her to falsify test results, reasoned the court. So, the court dismissed the case [*Penate v. Hanchett*, 2019 U.S. App. LEXIS 36956].

3 Takeaways

1. Lapses in supervision of lab workers can result in liability under §1983 if it results in falsification of test results or other actions that violate a person's constitutional rights.

2. Because §1983 also applies to non-government persons acting under "color of state law," liability is a potential risk not only for government-run labs but also private labs that perform drug or other testing in connection with law enforcement, public employment screening and other government functions.

3. The standard for supervisory liability under §1983 is significantly higher than ordinary negligence and requires evidence of deliberate indifference or ignorance that a subordinate is engaging in misconduct and that somebody's constitutional rights are being harmed as a result.

Compliance Corner: Must Employee Notify Lab of DUI?

QUESTION

If one of our employees gets a DUI, do they have to notify us?

ANSWER

It depends.

EXPLANATION

There are at least four factors affecting whether the employee would have to come forward and tell you about the DUI?

1. Your HR policies: What, if anything, do your current policies say about whether employees must notify you of their DUIs?

2. Conviction or arrest? If the employee was arrested but not convicted, he/she may be able to prove innocence (or may have already done so if the charges were dropped or the employee was acquitted). A conviction, on the other hand, would more likely affect job performance and thus require disclosure.

3. Impact on job performance: Notification is required if the DUI has an actual or potential impact on job performance, such as if:

- The employee needs to drive to do the job, e.g., a courier;
- The employee's job is safety-sensitive;
- The employee can't do the job with a revoked or suspended driver's license;
- The job requires the highest standards of morality and conduct, e.g., the employee is your ethics officer or in a sensitive public relations position.

4. On or off duty? Notification is almost sure to be required if the DUI happened while the employee was on duty.

Compliance Perspectives: Using Document Management Systems to Avoid HIPAA Pitfalls

By Andreas Rivera

One of the most challenging aspects of HIPAA compliance is ensuring that your methods of storing lab records containing protected health information (PHI) meet all of the law's privacy and security requirements. Regrettably, most HIPAA violations occur inadvertently without the lab's even realizing it. Here are five of the most common HIPAA violations to look out for:

1. Insufficient Access Control

Technological, physical and administrative measures need to be in place to ensure that access to records containing ePHI is limited to authorized lab employees for authorized purposes.

2. Not Removing Former Employees' Access

You need to ensure that employee with access to ePHI are barred from access as soon as their employment ends.

3. Lack of Encryption

Not using encryption or an equivalent solution for protecting electronic health records is a recipe for trouble.

4. Personal Email

Don't let employees use personal email accounts to store, use or transmit PHI.

5. PHI on Personal Devices

Similarly, be alert to the risk of employees' downloading PHI to their personal or other unauthorized electronic devices.

Overcoming the Challenge

For larger labs, a full-time HIPAA compliance officer is highly advisable. However, if you're a smaller lab with limited resources, you may have to rely on a tech solution. Digital solutions such as a shared network drive can be easier to handle, but hardly feature the security and privacy tools required by HIPAA. Lackluster cybersecurity is easy prey for hackers targeting you for ransomware. Document management software can be a lightweight solution for organizing medical records in a HIPAA-compliant manner.

The 3 Key Document Management System Features You Need

Make sure that any document management system solution you use includes three essential features and capabilities:

1. Customizable Security

Create security policies and apply them to different users and user groups. You can set password complexity requirements and even enable multi-factor authentication options.

2. Role-Based Permissions

You can create permission settings that can easily be attached to individual users as well as entire groups of users. Only authorized users should be able to access protected health records, while other users shouldn't even be able to see them in the system.

3. Audit Trail & Versioning

The system should be able to log everything that happens to a file, including when it was accessed, by which user account, and if it was changed. You can even revisit older versions of the document to see what exactly was changed.

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HIPAA Compliance: Quest Pays $195K to Settle Class Action for HIV Data Breach

Government fines, public embarrassment, loss of provider and patient trust. As if these consequences weren't scary enough, massive PHI breaches can expose your lab to a new kind of risk: class action lawsuits whose personal information was compromised. Exhibit A is the recent case against Quest Diagnostics.

The Quest Class Action

The case began in November 2016 when a massive cyberattack compromised the PHI of nearly 12 million people. Among the victims, the hackers were able to gain access to the SSNs, HIV test results and other personal information of Quest patients via the MyQuest by Care360 internet app. Rather than chase after Quest individually, a group of 34,000 victims banded together to bring a massive class action accusing Quest of negligently failing to safeguard their PHI and provide them timely notification of the breach, among other things.

Quest denies the allegations. And who knows what would have happened had the case proceeded to trial. But as is often the case when confronting the risk of not only liability but also liability multiplied by the number of class members, decided to settle the case. The cost: $195,000, including $250 to each individual who can demonstrate they suffered monetary loss as a direct result of the breach. Individuals who can show their HIV test results were accessed will be entitled to an additional $75.

OIG Work Plan: Agency to Focus on Vaccine Adverse Event Reporting

The five new items the OIG added to its Work Plan in December 2019 have no direct impact on labs or lab services, although three of them might have an indirect effect on some labs. Here's the rundown.

1. CDC Cybersecurity Controls Over the Vaccine Adverse Event Reporting System (VAERS)

Issue: Run by the CDC and FDA, VAERS is a national vaccine safety surveillance program that serves as an early warning system to detect

possible safety issues with U.S. vaccines by collecting information about adverse events (possible side effects or health problems) that occur after vaccination.

OIG Action: The OIG will do an audit of VAERS to determine whether federally required cybersecurity controls are in place.

2. Use of Technology for Emergency Response

Issue: During the 2017 and 2018 California wildfires, some responders used technology-driven tools such as data analytics to locate vulnerable Medicare beneficiaries in a disaster zone and a network of health information exchanges to access patients' electronic medical records and deliver care away from their typical care setting.
OIG Action: The OIG will do a case study addressing two uses of technology during the California wildfires for emergency response, to identify ways that entities can incorporate technology into their own emergency preparedness and response strategies.

3. National Background Check Program for Long-Term-Care Providers: Assessment of State Programs

Issue: The Affordable Care Act (ACA) authorizes CMS to provide grants to states via the National Background Check Program to implement background check programs for prospective employees and providers of long-term-care services. The ACA also requires OIG to evaluate the grant program after its completion.

OIG Action: The OIG will audit the implementation of select Program requirements for conducting background checks completed by states in 2019 to determine the outcomes of the states' programs and whether the checks led to any unintended consequences.

Industry Buzz: Supreme Court Declines Chance to End Agony of ACA Uncertainty

If you're worried about the fate of the *Affordable Care Act* and were hoping for a quick solution, forget it. On Jan. 21, the U.S. Supreme Court declined a Democratic request to fast-track the current federal case in Texas challenging the constitutionality of the law with a curt one-sentence saying no to rapid review for now but leaving open the possibility for a later date.

So Where Are We Now?

The ACA will remain valid law unless and until the following things happen:

- The Texas case runs its course, i.e., the U.S. Court of Appeals for the 5th Circuit issues a final decision on the merits; and
- The side that loses in the 5th Circuit appeals to the Supreme Court.

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After that, things get iffy. Although everybody expects the Court to accept the case, it could deny the appeal and leave the 5th Circuit ruling intact. And that would spell doom for the ACA if, as many expect, the 5th Circuit turns thumbs down on the law. Of course, there's always the possibility that the 5th Circuit will uphold the ACA. In that case, a Supreme Court denial to hear the appeal would end the challenge and ensure the law's survival.

The punchline is that none of this will happen until the 5th Circuit makes its ruling. The decision the 5th Circuit issued on Dec. 18 is not such a ruling. On the contrary, the court punted on the chance to rule on the merits and sent the case back down to the lower court to revisit and explain its earlier decision finding the entire ACA law unconstitutional. Why strike down the whole law and not just the individual mandate, the 5th Circuit asked the court to clarify.

Bottom Line: The 5th Circuit ruling only prolongs the agony since now the case has to go back down to the lower court, leaving the insurance market and millions of Americans to twist in the wind. The Democratic petition for fast-tracking was a chance for the Supreme Court to end the suspense, one way or another. But now that the Court has said no, the uncertainty will continue for at least another year.

Labs IN COURT

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

Reference Lab Pays $26.7 Million to Settle False Claim Charges

Case: The feds claim that Laboratory Boston Heart Diagnostics contracted to provide lab testing services to Texas hospitals in exchange for per-test payments and then orchestrated the creation of management service organizations (MSOs) to generate referrals to the hospitals. The alleged role of the MSOs was to identify referring physicians interested in being paid kickbacks disguised as investment returns in exchange for referrals. Rather than risk a trial, Boston Heart agreed to settle the claims for $26.67 million, of which the whistleblowers who brought the suit will pocket roughly $4.36 million.

Significance: Reference lab arrangements in which a provider outsources the performance of tests it's contractually required to provide to an outside lab at a rate below the contracted reimbursement price have become a prime target for federal enforcers and private payors. In addition to false billing red flags, these arrangements raise kickback concerns when MSOs are used to recruit physicians and generate referrals to the reference lab.

Lab Gets Chance to Prove Fraud Claims against Software Vendor at Trial

Case: After being hit with a slew of CLIA penalties, a toxicology lab hired a software and IT services firm to help get its information systems back into compliance. But while progressing toward recertification, the lab

discovered glitches in the software, including a defect leading to duplicate container numbers for patients and a Trojan Horse resulting in passwords and other security information being discoverable on Google. The lab sued the firm for fraud. The firm asked for summary judgment, i.e., dismissal without a trial but the Louisiana court said no dice.

Significance: To prove misrepresentation, the lab would have to show three things: (i) the firm made a misrepresentation about the software; (ii) it did so deliberately to gain an unjust advantage or damage the lab; and (iii) the lab relied on the misrepresentation in buying the software. The lab had evidence to support each of these allegations. Although not enough to prove the allegations, at this point in the proceedings it was adequate to allow the case to go forward and give the lab the opportunity to prove the claims at trial [Trinity Med. Servs., LLC v. Merge Healthcare Sols., 2020 U.S. Dist. LEXIS 2424, 2020 WL 97162].

Lab Pays $311K for Giving Physicians Free Specimen Collection Supplies

Case: Histopathology Services LLC d/b/a Pathline Emerge (Pathline), New Jersey, will fork over $310,978 after self-disclosing to the OIG that it violated kickback laws by giving physicians free medical collection supplies.

Significance: As was vividly demonstrated in the Millennium Health case, free supplies to facilitate the collection of specimens may constitute remuneration banned by the Anti-Kickback Statue and Stark Laws. Ditto for fees paid to physicians to collect and process the specimens they send to your lab. (For more details, see Lab Compliance Insider, (LCA), Dec. 10, 2018.)

Lab Management Contract Dispute Must Go to Binding Arbitration

Case: A lab management services contract sent conflicting messages: Clause 32 said that all disputes under the contract would be resolved by binding arbitration; but Clause 7 said that all claims under the agreement would be submitted to the federal court in New Jersey. So, when a dispute broke out and the lab sued, the management firm asked the court to send the case to arbitration. The court refused. Parties must use clear and unambiguous language to waive their right to a court trial, it reasoned. And the fact that they stuck Clause 7 into the agreement undermined the required clarity. However, the appeals court reversed.

Significance: The appeals court relied on technicalities that you need to be aware of in negotiating your own contracts:

- There's a law called the Federal Arbitration Act that governs the interpretation of arbitration clauses in contracts transacting interstate commerce (as was the case here);
- The FAA requires courts to enforce binding arbitration when the parties show a clear intent to arbitrate;
- According to court cases, a provision indicating the parties' agreement

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to conduct the arbitration in accordance with the American Arbitration Association (AAA) is evidence of such an intent; and

- Clause 32 included such a clause.

Bottom Line: If your lab contracts with a party from a different state and wants to ensure disputes will be decided by arbitration rather than litigation, make sure the arbitration clause includes language like the

> The parties agree that the arbitration to take place under this Agreement will be performed in accordance with the commercial arbitration rules of the American Arbitration Association (AAA), which are hereby incorporated into this Agreement.

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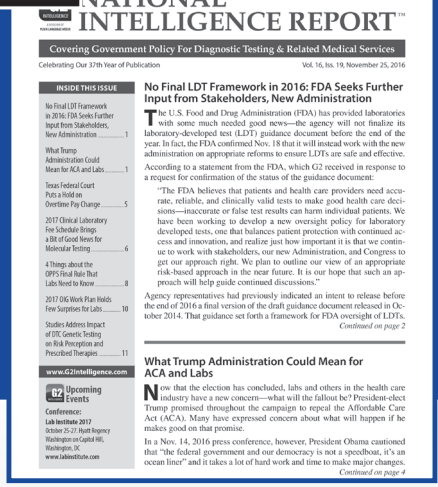
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