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LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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IN THIS ISSUE

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Compliance Perspectives: Using Waivers to Avoid Getting Sued for COVID-19 Infections

PLEASE READ

NOTICE TO ALL ENTRANTS AND USERS
OF THESE LABORATORY FACILITIES

EXCLUSION OF LIABILITY – ASSUMPTION OF RISK

THESE CONDITIONS WILL AFFECT YOUR LEGAL RIGHTS INCLUDING THE RIGHT TO SUE OR CLAIM COMPENSATION FOR AN INJURY OR ILLNESS

In these times of pandemic, signs and forms like this purporting to shield the owner of a facility against liability have become a fixture in workplaces and other facilities. You might even be using them at your own lab. The idea is to notify patients, vendors and other visitors (which, for simplicity's sake, we'll refer to collectively as "visitors") that they're entering the facility at their own risk and in so doing, waiving their rights to sue the owner for any illness or injury they suffer while on the premises. Of course, that includes COVID-19 infection. It seems like a simple, cost-effective way

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Whistleblowers: Relying on the First-to-File Rule to Protect You from Copycat *Qui Tam* Lawsuits

As you know, the private individuals, known as relators, the right to bring *qui tam* lawsuits on the government's behalf against labs and other contractors that submit false claims to the federal government. But what happens when multiple relators bring separate *qui tam* suits against a lab for the same basic offense? **The Rule:** Under the False Claims Act (FCA), the first whistleblower to file is the only one allowed to bring the case. This principle, known as the "first-to-file" rule is designed to protect labs from copycat suits. However, the rule applies only if the subsequent

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Compliance Perspectives: Using Waivers to Avoid Getting Sued for COVID-19 Infections, *from page 1*

to limit liability risks to visitors who may claim they got infected while they were at your lab. But will it work?

The answer may depend, in large part, on how you draft your waiver.

Your Potential Liability for Visitors' COVID-19 Infections

OSHA laws require you to protect workers against COVID-19 infection by following current public health guidelines on social distancing, hygiene, disinfection, etc. Failure to do so can result in stop-work orders, OSHA fines, workers' comp claims and other nasty legal consequences. But for the most part, you won't have to worry about getting sued by your workers because workers' comp laws bar workers from suing their employers for work-related illnesses and injuries.

However, workers' comp doesn't bar lawsuits by non-workers who get ill or injured while visiting your facility. Stated differently, as the owner of a facility, you have a legal duty to protect visitors. That duty stems principally from two laws:

- **Negligence law:** Visitors who contract COVID-19 as a direct consequence of your failure to use reasonable care to protect them can sue your lab for money damages to compensate them for the losses they suffered as a result; and
- **Occupiers' liability laws:** Visitors who get infected at your property can also sue for money damages under statutes found in many states and municipalities that require the occupier of a property to keep visitors reasonably safe from harm when they enter it.

The Liability Waiver

The liability waiver, aka release or exculpatory agreement, is designed to limit legal risks by getting another person to waive, i.e., voluntarily give up, their legal right to sue for injuries or damages. While workers' comp makes them unnecessary for workers, waivers may be valuable in limiting potential liability to visitors.

There are two ways to go about getting a COVID-19 waiver from visitors:

- Having the visitor sign a written waiver agreement; and/or
- Posting a sign notifying visitors that by entering the facility, they agree to waive their rights to sue for infections they may contract on the premises.

The big question: Would a court actually enforce these waivers?

Although there hasn't yet been a COVID-19 waiver case, centuries of waiver litigation provides pretty reliable clues of how courts would decide such a claim when they inevitably do arise.

LCA

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4 COVID-19 Waiver Pitfalls to Avoid

The starting point is that courts won't enforce waivers if they think the property owner is taking advantage. So, as lab manager, you need to be aware of the red flags.

1. Lack of Negotiation

A fundamental problem with waivers is the disparity in negotiating power between the property owner and the visitor granting the waiver. In fact, waivers are rarely actually negotiated. The owner creates the waiver and requires the visitor to sign it. And, in the case of a sign, the waiver doesn't even require a signature to take effect. However, courts will still enforce sign waivers, provided that they're conspicuously posted at the entry and the owner can prove the visitor actually saw them.

2. Lack of Clarity

Another problem with waivers is that they tend to be laden with legal jargon and boilerplate content, often in very small print that visitors are highly unlikely to read, let alone understand. That's why courts will only enforce a waiver if it's clear and unambiguously written in a way that ensures the reader understands both the hazards to which they're exposed by entering the facility and the rights they're giving up. In the context of COVID-19, that requires spelling out the risks of infection and plainly stating that the waiver means that the visitor won't be able to sue you if he or she thinks they contract the virus at your lab facility.

3. Lack of Consideration

Contractual promises and obligations aren't enforceable unless the person who makes them receives consideration, i.e., something of value in return. The COVID-19 waiver, therefore, needs to provide for such consideration, namely, gaining entry to the lab facility.

4. Unconscionability

"Unconscionability" is the legal term used by courts to describe an agreement that's unenforceable because it's so unfair and one-sided in favor of the person that drafted it. Similarly, a court may deem the waiver unenforceable as being contrary to public policy. Although each case is different, there are some fairly clear lines that would probably apply to a COVID-19 waiver. As a rule, the broader the waiver and scope of conduct it purports to excuse, the harder it will be to enforce:

- Most Enforceable: Waiver of the visitor's right to sue for COVID-19 infection that wasn't the lab's fault;
- Possibly Enforceable: Waiver of the visitor's right to sue for COVID-19 infection even if it was the result of the lab's negligence;
- Unenforceable: Waiver of the visitor's right to sue for COVID-19 infection attributable to the lab's intentional, reckless or grossly negligent conduct.

MODEL TOOL

VISITORS' WAIVER OF COVID-19 INFECTION LIABILITY FORM

As long as COVID-19 remains a threat, you run the risk of being sued by patients, vendors, guests and other visitors ("visitors") who claim they contracted the virus at your lab facility as a result of your inadequate safety measures. One way to limit liability is having visitors sign a form agreeing to waive their rights to sue you for COVID-19 infections before entering the lab. Although there's no guarantee that a court would enforce such a waiver, the Model Form below uses fairly conservative language that has been found to be enforceable in other situations. Caveat: The inclusion of the phrase purporting to insulate you against your own negligence in Sections 3 and 4 is fairly risky and you may want to talk to counsel about whether to use it in your own waiver.

WAIVER & RELEASE OF LIABILITY FOR COVID-19 INFECTION

1. I am fully aware that COVID-19 is a highly contagious disease that can result in a serious medical condition requiring hospitalization and possibly death either to myself or others including family members that contract COVID-19 as a result of contact with me. I am also fully aware that by entering the XYZ Laboratories facility (the "Facility"), I am assuming the risks of contracting COVID-19 notwithstanding the infection control measures XYZ Laboratories has put in place to protect workers and visitors at the Facility.
2. I agree that I am personally responsible for my safety and actions at all times when I am present at the Facility and will comply with all XYZ Laboratories policies and rules, including but not limited to with regard to social distancing, hygiene, use of personal protective equipment and other policies, procedures, guidelines, instructions and signage relating to prevention of COVID-19 infection.
3. With full awareness and appreciation of the risks involved, and in consideration for being permitted to enter and remain at the Facility and receive the services provided inside it, I, for myself and on behalf of my family, spouse, estate, heirs, executors, administrators, assigns and personal representatives, hereby forever release, waive, discharge, and covenant not to sue XYZ Laboratories, its board members, officers, agents, servants, independent contractors, affiliates, employees, successors and assigns (collectively the "Released Parties") from any and all liability, claims, demands, actions, and causes of action whatsoever, directly or indirectly arising out of or related to any loss, damage, or injury, including death, that may be sustained by me related to COVID-19, [whether caused by the negligence of] the Released Parties, any third-party using the Facility, or otherwise, while participating in any activity while in, on, or around the Facility and/or while using any XYZ Laboratories facilities, tools, equipment or materials.
4. I agree to indemnify, defend and hold harmless the Released Parties from and against any and all costs, expenses, damages, claims, lawsuits, judgments, losses and/or liabilities (including legal fees) arising either directly or indirectly from or related to any and all claims made by or against any of the Released Parties due to bodily injury, death, loss of use, monetary loss or any other injury from or related to my use of the Facility, tools, equipment, or materials, [whether caused by the negligence of] the Released Parties or otherwise specifically related to COVID-19.
5. By signing below I acknowledge and represent that I have read the foregoing Waiver of Liability, understand it and sign it voluntarily as my own free act and deed, including without limitation the Release of Liability and Indemnification requirements contained in this document; I am sufficiently informed about the risks involved in being present at the Facility to make a voluntary decision about whether to sign this document; no oral representations, statements or inducements, apart from the foregoing written agreement, have been made; I am at least eighteen (18) years of age and fully competent; and I execute this document for full, adequate, and complete consideration fully intending to be bound by the same. I agree that this Wavier of Liability shall be governed by and construed in accordance with [state] law, and that if any of the provisions hereof are found to be unenforceable, the remainder shall be enforced as fully as possible and the

unenforceable provision(s) shall be deemed modified to the limited extent required to permit enforcement of the Waiver of Liability as a whole.

Print Name _____ Date_____

Signature_____

MODEL TOOL

WAIVER OF COVID-19 INFECTION LIABILITY SIGN TO POST AT YOUR LAB

As long as COVID-19 remains a threat, you run the risk of being sued by patients, vendors, guests and other visitors ("visitors") who claim they contracted the virus at your lab facility as a result of your inadequate safety measures. One way to limit liability is by conspicuously posting a sign at the entry of your facility indicating visitors' agreement to waive their rights to sue you for COVID-19 infections by entering the lab. Although there's no guarantee that a court would enforce such a waiver, the Model Sign below uses fairly conservative language that has been found to be enforceable in other situations. Caveat: The inclusion of the phrase purporting to insulate you against your own negligence in Sections 3 and 4 is fairly risky and you may want to talk to counsel about whether to use it in your own waiver sign.

WAIVER OF COVID-19 LIABILITY
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I am aware that COVID-19 is a highly contagious disease that can result in a serious medical condition requiring hospitalization and possibly death either to myself or others including family members that contract COVID-19 as a result of contact with me. I agree that by entering the XYZ Laboratories facility (the "Facility") and receiving the services it provides or using the equipment, tools and materials it contains, I am assuming the risks of contracting COVID-19 and that I am personally responsible for my safety and actions at all times when I am present at the Facility and will comply with all XYZ Company policies and rules. With full awareness and appreciation of the risks involved, and in consideration for being permitted to enter and remain at the Facility and receive the services provided inside and/or use the tools, equipment or materials inside it, I, for myself and on behalf of my family, spouse, estate, heirs, executors, administrators, assigns and personal representatives, hereby forever release, waive, discharge, and covenant not to sue and indemnify and hold harmless XYZ Laboratories, its board members, officers, agents, servants, independent contractors, affiliates, employees, successors and assigns (collectively the "Released Parties") from any and all liability, claims, demands, actions, and causes of action whatsoever, directly or indirectly arising out of or related to any loss, damage, or injury, including death, that may be sustained by me related to COVID-19, [whether caused by the negligence of] the Released Parties, any third-party using the Facility, or otherwise, while participating in any activity while in, on, or around the Facility.

Labs IN COURT

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

Referral Arrangement Violates Kickback Laws Even If Even Only Purpose Is to Generate Illegal Referrals

Case: The U.S. Attorney accused a Kentucky physician of taking a $105 per beneficiary payment from a lab company in exchange for ordering its pharmacogenetic tests in violation of the Anti-Kickback Statute (AKS). And since the company billed Medicare for the tests, the physician "caused" a fraudulent claim to be submitted in violation of the False Claims Act (FCA). The physician asked the court to dismiss the charge because the government didn't allege that he entered into the fee arrangement for the "sole purpose" of generating illegal referrals. And if the underlying AKS violation wasn't an actual violation, the subsequent billing by the lab for the tests wasn't an FCA violation either, he reasoned. But the Kentucky federal district court disagreed and allowed the FCA claim to go forward.

Significance: The physician claimed that his motives were mixed at best since he ordered the tests before entering into the fee referral agreement with the lab company. But the volume of referrals increased dramatically once the arrangement was in place and then decreased when the lab company cut the referral fee. More importantly, the court reasoned that an arrangement runs afoul of the AKS if even one of its purposes is to generate illegal referrals even if it's not the sole motivation [*United States v. Vora*, 2020 U.S. Dist. LEXIS 173000].

BioReference Labs Shells Out $11.5 Million to Settle Kickback and False Billing Charges

Case: The feds claimed that from 2009 to 2012, BioReference Laboratories billed Medicare TRICARE for hospital inpatient tests listed on the Part B Clinical Lab Fee Schedule even though those tests were covered by the hospital's Part A inpatient prospective bundled payment and thus should have been billed to the hospital. Consequently, the government ended up paying for those tests twice. Rather than risk a trial, BioReference agreed to settle the charges for $11.5 million.

Significance: In addition to the $1.4 million covering the improper billing, the settlement includes $10.1 million covering allegations that BioReference donated the cost of electronic medical records software to physicians' practices "based solely on the volume of business" those practices generated. The settlement agreement requires BioReference to admit to paying for EMR software to 69 practices based on whether the revenues generated by the particular office would equal three times the software's value.

OSHA Fines New Jersey Hospital for Coronavirus Respiratory Protection Violations

Case: OSHA is proposing to fine the hospital $9,639 for two serious violations: i. Failure to fit test tight-fitting respirators face piece respirators

on employees required to use them; and ii. Not training employees on proper respirator use and ensuring employees understood when they must wear a respirator.

Significance: Although the total penalty amount is fairly minor by OSHA standards, the thing lab managers should take away from this case is that OSHA inspectors are out in the field doing targeted inspections to determine if health care facilities are complying with their COVID-19-related responsibilities. Thus, a week after the New Jersey case, OSHA fined a Massachusetts dental practice $9,500 for lack of fit-testing and five other serious violations of respiratory protection, bloodborne pathogen and hazcom requirements.

Liability Insurer Doesn't Have to Defend Lab in Malpractice Suit

Case: A blood and urine drug testing lab had to wage malpractice litigation on two fronts: one against the rehab clinic who claimed that the lab's false reporting of drug tests harmed its reputation and business; and the other against a patient who claimed that false testing results caused social services to take her child out of her custody. To make matters worse, the lab's liability insurer claimed it had no obligation to indemnify or defend the lab from the charges because of the "professional services" exclusion of the policy. The federal court agreed and issued a declaration to that effect.

Significance: Because coverage exclusions undermine the fundamental protective purpose of insurance, courts interpret them strictly construed against the insurer. However, the court found that the professional services exclusion in this policy was "clear and unequivocal," particularly the language excluding "claims alleging negligence or other wrongdoing in the supervision, hiring, employment, training or monitoring of others by an insured. . . . [involving] the rendering or failure to render of any professional service." The accusations against the lab all involved wrongdoing in sample taking and results reporting that fit squarely within the scope of the exclusion, concluded the court [*State Farm Fire & Cas. Co. v. Compliance Advantage*, 2020 U.S. Dist. LEXIS 118778, 2020 WL 3800517].

Quiz: Lab's Duty to Protect Returning Employees from COVID-19 Discrimination and Harassment

SITUATION

Fully recovered from his bout with COVID-19, Max is thrilled and excited to return to his custodian job after 14 days of mandatory home isolation. But almost immediately, he senses that something is wrong. His co-workers shun him and leave the room the moment

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Quiz: Lab's Duty to Protect Returning Employees from COVID-19 Discrimination and Harassment, *from page 7*

he enters. And, while hygiene and handwashing are *de rigeur* for all maintenance staff, Max alone is required douse his hands in germicide and don rubber gloves each time he touches a piece of equipment. Worse, his supervisor harasses him and calls him "virus boy." After weeks of putting up with it, Max complains to lab management. But his complaints fall on deaf ears and he continues to be ostracized and made to take extraordinary safety and hygiene measures not required of anybody else. So, he hires a lawyer and sues the lab for disability discrimination.

QUESTION

Does Max have a valid case for disability discrimination?

A. No, because the differential treatment he received were legitimate health and safety measures

B. No, because while actually having COVID-19 may be deemed a disability, Max is fully recovered

C. Yes, because he was forced to go into self-isolation because he had COVID-19

D. Yes, because he was treated differently because he was perceived as having COVID-19

ANSWER

D. Max has a valid case because he was harassed and saddled with additional health and safety burdens due to the perception of having COVID-19.

EXPLANATION

Almost the moment the pandemic began, the U.S. Equal Employment Opportunity Commission (EEOC) made it clear that it considers COVID-19 to be a disability protected from discrimination under the Americans with Disabilities Act (ADA). As a result, subjecting an employee (or job applicant) to differential and unfavorable treatment because they have COVID-19 is disability discrimination. This is also true if that differential treatment is based on the mere belief that the employee or job applicant has the virus, even if that perception is wrong.

This scenario, which is purely hypothetical, is designed to illustrate how those principles play out in real life. The point is that Max was harassed, stigmatized and singled out because he once had COVID-19 and was, wrongly, perceived as posing a greater risk of infection. So, D is the right answer.

WHY THE WRONG ANSWERS ARE WRONG

A. is wrong because Max was shunned and forced to take health and safety measures required of no other maintenance employee all

because he once had COVID-19. It's important to note that there's no scientific evidence to support the notion that people who had the virus are more apt to transmit it to others after they recover; in fact, people recovering from COVID-19 pose a lesser risk because they have antibodies to fight the virus.

B. is wrong because a person who doesn't have COVID-19 can be considered disabled if he/she is perceived as having it. Thus, adverse treatment resulting from being perceived to be disabled is discrimination, even if that perception is wrong. Legally, Max's situation is like a job applicant who gets rejected because the lab wrongly believes him to be a drug addict.

C. is wrong because while being forced to self-isolate due to COVID-19 is differential treatment based on a disability, the EEOC has acknowledged that it's a justifiable health and safety measure during the pandemic, one that's also required under current public health guidelines.

Employment Law: EEOC updates COVID-19 guidance

By Mike O'Brien

The Equal Employment Opportunity Commission (EEOC) recently updated its COVID-19 guidance page, addressing a number of issues. Here are some of them:

On coronavirus testing, the EEOC said general testing administered by employers consistent with current CDC guidance will meet the ADA's "business necessity" standard, and noted that employers should ensure that the required COVID-19 tests are accurate and reliable according to the FDA, CDC, and other public health authorities. If an employer wants to test only one employee, however, the employer should have a reasonable objective belief that he/she might have the disease. The EEOC says an employer can ask employees whether they have had contact with anyone diagnosed with COVID-19 or who may have symptoms associated with the disease, but should not phrase that question as one asking about family members.

Moreover, the EEOC says the ADA allows an employer to bar an employee from physical presence in the workplace if he/she refuses to have a temperature taken or refuses to answer questions about whether he/she has COVID-19, has symptoms associated with COVID-19, or has been tested for COVID-19.

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Employment Law: EEOC updates COVID-19 guidance, *from page 9*

Test and screening results are confidential, but without identifying the involved employee, an employer can give notice to others in the workplace that someone has COVID. The EEOC explains, "For example, using a generic descriptor, such as telling employees that 'someone at this location' or 'someone on the fourth floor' has COVID-19, provides notice and does not violate the ADA's prohibition of disclosure of confidential medical information. Confidentiality must be maintained even within the home where a supervisor or HR person is remotely working, thus the EEOC says, "This means that paper notepads, laptops, or other devices should not be left where others can access the protected information."

Allowing telework now does not mean an employer must allow it when the pandemic ends, as EEOC says, "The fact that an employer temporarily excused performance of one or more essential functions when it closed the workplace and enabled employees to telework for the purpose of protecting their safety from COVID-19, or otherwise chose to permit telework, does not mean that the employer permanently changed a job's essential functions, that telework is always a feasible accommodation, or that it does not pose an undue hardship. These are fact-specific determinations." Yet, EEOC also notes, "The period of providing telework because of the COVID-19 pandemic could serve as a trial period that showed whether or not [an] employee with a disability could satisfactorily perform all essential functions while working remotely." You can read the updated guidelines here: Updated EEOC COVID-19 Guidelines.

Mike O'Brien *of Jones Waldo is an employment attorney, media lawyer and courtroom litigator. He is leader of the firm's Employment Law and Media Law practice groups. Mike works with the local and national Society for Human Resource Management (SHRM) and serves as the legal and legislative director for Utah SHRM and Salt Lake SHRM. For such services, National SHRM honored him with its prestigious Capital Award, given annually to one of SHRM's 170,000 members worldwide. Mike partners with employers in many industries to prevent and solve employment problems. He writes Employment Law Update, a regular column on the G2 Intelligence website.*

Whistleblowers: Relying on the First-to-File Rule to Protect You from Copycat *Qui Tam* Lawsuits, *From Page 1*

suits are "related to" the first suit. And, as illustrated by the following cases, courts use two divergent approaches in interpreting the meaning of "related," one which is favorable to whistleblowers and one which is favorable to labs.

Subsequent Whistleblowers Win

Some courts interpret "related" very narrowly and allow subsequent whistleblowers to get around the first-to-file rule as long as they introduce unique information or aspect not addressed in the first case. Here's an example.

What Happened

Three different *qui tam* suits were filed against Inform Diagnostics (which was then known as Miraca Life Sciences Inc.) for allegedly offering physicians discounts on electronic health records (HER) consulting services in exchange for lab referrals. The whistleblowers included Miraca's former Life Science Sr. Vice President of Commercial Operations, dermapathologists and a company called LPF LLC, which claimed that Inform/Miraca limited the discount deal to physicians it identified as potentially high-volume referral sources and based individual discount amounts on the anticipated return on investment the particular physician's referrals would generate. Informa/Miraca asked the court to dismiss two of the three cases under the first-to-file rule.

The Ruling

The Tennessee federal court denied the motion to dismiss and allowed all three claims to proceed. Faced with the prospect of having to defend itself in three different trials, Informa/Miraca agreed to pay $63.5 million to settle the claims.

The Reasoning

Even though all three complaints stemmed from the same alleged scheme, the court held that the first-to-file rule didn't apply because each of the whistleblowers offered unique information about how Informa/Miraca carried out the scheme. Each relator shed light on a different aspect of the arrangement explaining how the lab offered and paid referring physicians kickbacks in the form of discounted HER consulting services in exchange for referrals, it concluded.

United States ex rel. Dorsa v. Miraca Life Sciences, Inc., Case No. 13-cv-1025 (M.D. Tenn.); *United States ex rel. LPF, LLC v. Miraca Life Sciences, Inc.*, et al., 3:16-cv-1355 (M.D. Tenn.); and *United State ex rel. Heaphy, et al. v. Miraca Life Sciences, Inc.*, 3:18-cv-1027 (M.D. Tenn.)

Subsequent Whistleblowers Lose

Other courts interpret "related" far more expansively and apply it if the claims involve the "same material elements," even if the subsequent case introduces something new or novel.

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Whistleblowers: Relying on the First-to-File Rule to Protect You from Copycat *Qui Tam* Lawsuits, *from page 11*

What Happened

A group of whistleblowers filed a *qui tam* suit charging Logan Labs and Surgery Partners with running a kickback scheme to get physicians to order medically unnecessary confirmatory urine drug tests (UDT) that were then billed to Medicare. While the case was pending, another group of whistleblowers brought a case involving the same scheme but naming as defendant not Logan or Surgery Partners but rather H.I.G. Capital, the equity firm that owned them, for its role in the scheme. H.I.G. asked the court to dismiss the second case.

The Ruling

The Florida federal court ruled that the second case was "related" to the first case and dismissed it under the first-to-file rule.

The Reasoning

"Assessing relatedness is not rocket science," noted the court. All it requires is comparing the complaints side-by-side "to see whether the claims in the second action incorporate the same material elements of fraud." In this case, they did. True, H.I.G. wasn't a defendant in the first suit—although they were named as Logan's and Surgery Partners' corporate owner; and the new suit focused on H.I.G.'s masterminding the scheme as a corporate owner of related entities, something the first case didn't even bring up. But, at the end of the day, both complaints were about the same thing, namely, a broad, nationwide scheme by Logan Labs and Surgery Partners to defraud Medicare and other government programs by submitting medically unnecessary and inflated claims for UDT.

United States ex rel. Cho v. H.I.G. Capital, LLC, 2020 U.S. Dist. LEXIS 155373

Takeaway

Of the two standards for interpreting whether subsequent whistleblower lawsuits, the more defendant-friendly "same material elements" approach is more common, followed by seven of the 12 federal circuits. And that list may grow by one to include the Eleventh Circuit if the H.I.G. case is appealed and is affirmed by the U.S. Court of Appeals.

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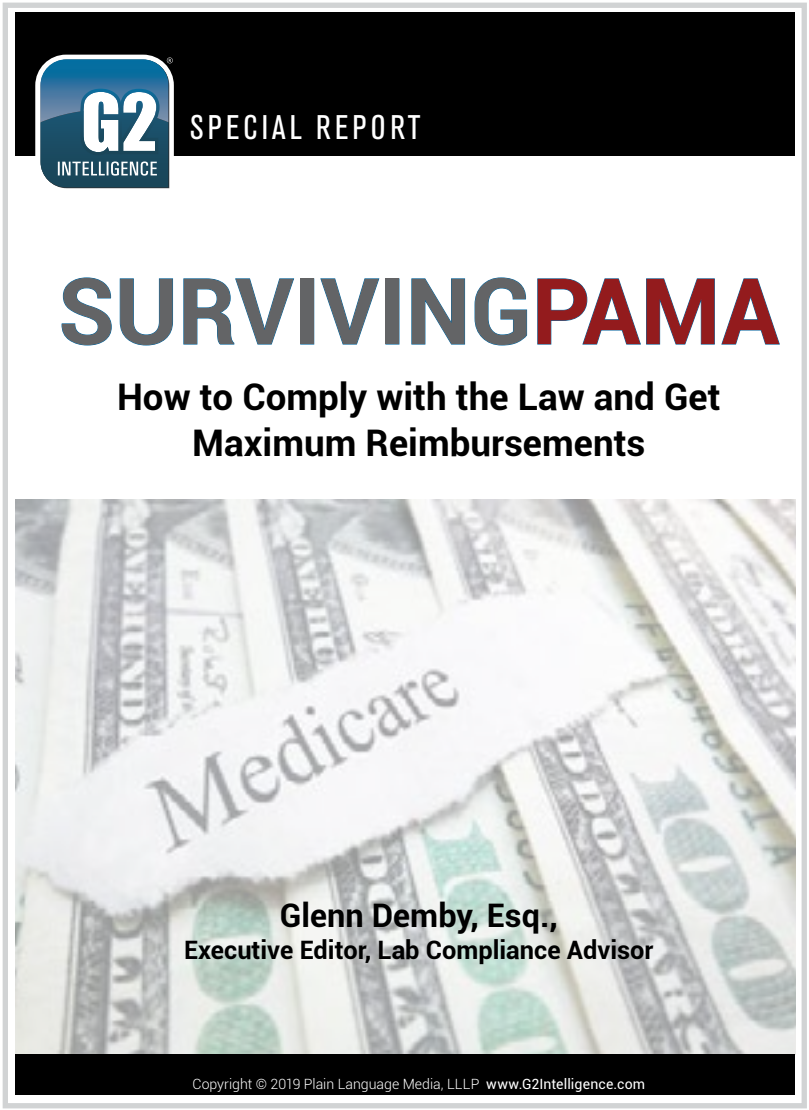

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