G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

LAB Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

February 2021

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Compliance Perspectives: How to Audit the Effectiveness of Your Lab Compliance Plan

If you're reading this, it's a pretty good bet that you've put a compliance plan into place at your lab. But just how effective is it? To answer this crucial question, you must consider not only what your compliance plan says but how it's implemented. After all, even the most carefully drafted of plans can lose their effectiveness over time if they're not scrupulously monitored, measured and adjusted. Here's a strategy you can use to evaluate how well your own compliance plan is working.

The 3 Key Indicators of Lab Compliance Plan Effectiveness

Internal monitoring and prompt corrective action are two of the seven critical elements of an effective lab compliance program listed in the OIG guidelines first published back in 1997 and revised in 1998. The key to carrying out those activities is to focus on those other elements. Specifically,

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Courts to Whistleblowers: No Lawyer, No *Qui Tam* Lawsuit

It takes a lot of gumption to sue your own employer for the good of the federal government. But while the *False Claims Act* (FCA) authorizes whistleblowers to file *qui tam* lawsuits on the government's behalf, there's one thing it doesn't allow them to do: Act as their own attorney in the case. This might seem like a minor point, but it can have game changing repercussions in actual cases, especially if a whistleblower tries to sue your lab without being represented by counsel.

Federal Court Rejects Whistleblower's Pro Se Lawsuit

A whistleblower from New Jersey learned this lesson the hard way. It was a rather strange case that began when a woman called the police claiming that her daughter was threatening her with a knife. The daughter vehemently denied the charge

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audits and compliance plan assessment should focus on three key indicators.

The 7 Elements of an Effective Lab Compliance Program

1. Written policies, procedures and standards of conduct
2. Establishment of a compliance officer and committee
3. Ongoing compliance training and education
4. Effective lines of communication
5. Disciplinary guidelines for enforcement
6. Internal monitoring and auditing
7. Prompt response to offenses and corrective action plans

1. Compliance Education and Training

Effectiveness of compliance education and training is critical and requires the existence of, at a minimum:

- Initial training and orientation of new lab employees;
- Annual training on core compliance topics like kickbacks, medical necessity and reporting of violations;
- Annual training on special topics based on regulatory developments, such as genetic testing, COVID-19 and PAMA data reporting and telemedicine;
- Periodic training on high-risk issues, e.g., lab policies on providing gifts and entertainment to physicians and other referral sources for marketing representatives; and
- Just-in-time training when policies and procedures change.
- Verify that all forms of training are documented and verified for effectiveness, e.g., via quizzes to measure how well trainees understood the materials. Simple acknowledgement of receiving and understanding of training by trainees is generally insufficient to prove that training actually sunk in, experts caution.

2. Internal Communication

Be sure to focus on whether effective lines of communication are in place and are actually being used by lab employees. **Best Practice:** Internal communication systems should include three elements, including a mechanism for employees to:

- Discuss compliance issues or concerns with an immediate supervisor;
- Go over the supervisor's head and report concerns to a manager or directly to the compliance officer, if necessary; and
- Report issues or concerns anonymously on a 24/7 basis such as a compliance hotline.

Of course, simply having these mechanisms isn't enough without implementing measures to promote their use, including ensuring that

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Lab Compliance Advisor (ISSN 2332-1474) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

employees are aware of the lines of communication and that supervisors and managers are approachable. It's also critically important to have and scrupulously implement a clear and strongly worded anti-retaliation policy. Last but not least, there should be a way to loop back with employees who report compliance problems to let them know what you're doing to investigate their concerns. After all, failure to ensure employees that you're taking reported violations seriously is a surefire recipe for whistleblower lawsuits.

3. High-Risk Issues

When auditing the effectiveness of your lab compliance plan, focus on high-risk issues like:

Order/Report/Bill review: Review lab requisitions and orders, reports, claim forms and attached documents (including any Medicare secondary payor forms) to ensure that what the provider ordered matches what was billed, including reflex testing. Verify that the ICD-10 code on the requisition or order matches the claim and that, if necessary, a proper advanced beneficiary notice was executed.

Standing orders: Review standing orders to ensure they meet OIG standards with regard to patient specificity in terms of tests ordered and time intervals. Verify that all standing orders are signed by the provider that authorized them and that those orders were reviewed or renewed no less than once a year.

Custom profiles: Review the custom profile authorization form to ensure that it contains all of the required details and effectively notifies the ordering provider the components of each profile and how much each individual item costs. Verify that each profile component is medically necessary and that the provider signs an annual notification form for the panel.

Three-day payment window: Hospital and outreach labs that are wholly owned or operated by the hospital should review inpatient admission reports and lab test orders to verify that testing was performed on inpatients within three days (and not 72 hours) of admission and that testing was billed as a separate claim under Part B, rather than rolled into the Part A diagnosis related group.

PAMA and COVID-19 reporting: Verify that your lab has met its reporting obligations with respect to both pricing information for tests performed and demographic and other patient and information required by the new COVID-19 CMS COVID-19 test reporting rules that took effect in August 2020.

CPT/HCPCS coding: Go over your procedures for maintaining current and accurate CPT and HCPCS codes and that new tests and diagnostic methods, including but not limited to those for COVID-19, are being correctly coded and communicated to the billing system.

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Test utilization: Review the top 30 tests ordered in the past 12 months vis-à-vis the top 30 tests ordered in the 12 months before that. Did any of those increase by more than 10 percent year to year? If so, ensure that you can justify and document the reason(s) for the increase recognizing that government auditors will see the increase as a red flag.

Marketing issues: Review marketing brochures, client supply reports, contracts with ordering physicians and other referral sources, test requisitions, test directories, marketing expense reports and client fee schedules to verify that:

- Marketing materials are clear and not in any way misleading;
- Supplies sent to clients are appropriate for the volume of tests ordered;
- Payments under leases, phlebotomy services agreements and other contracts with referral sources are at fair market value, properly executed and in accordance with all applicable Stark Law and Anti-Kickback Statute (AKS) exceptions and safe harbors;
- Requisitions offer providers clear choices about which tests to order; land
- Any gifts and "non-monetary compensation" to referral sources meet Stark and AKS standards.

Exclusion checks: Last but not least, review federal exclusion databases to ensure none of your current employees, vendors, clients or other business affiliates are listed on them. Make sure your checks account for and provide the necessary disclosures under the strict CMS Medicare affiliates exclusion rules that took effect in 2019. See "The New CMS Medicare Exclusion Rules & How to Comply," *Lab Compliance Advisor*, (LCA), Oct. 28, 2019.

Labs IN COURT

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

$4.3 Million Is Too High a Penalty for HIPAA Violation, Says Federal Court

Case: A federal appeals court has shot down what had been the fourth largest OCR penalty for a HIPAA violation as having "no lawful basis." That decision means that instead of $4.3 million, the University of Texas MD Anderson Cancer Center will have to pay $450,000 for failing to encrypt protected patient data. OCR doled out the fine in 2018 to settle alleged HIPAA violations associated with a trio of separate data breaches that occurred in 2012 and 2013, involving the loss and theft of an unencrypted laptop and two unencrypted flash drives containing data on approximately 33,800 patients.

Significance: HIPAA requires covered entities to "implement a mechanism to encrypt and decrypt" ePHI. There was no dispute that Anderson fell short in meeting this requirement. The issue was how big a penalty it deserved. It wasn't like Anderson was cavalier. There were policies and training in place. But the employees involved in the breaches apparently didn't follow them. The mechanism existed, "even if it could or should have been better," the Fifth Circuit reasoned. The court also found that OCR failed to abide by per-year penalty caps for HIPAA violations.

[*University of Texas M.D. Anderson Cancer Center v. U.S. Dept. of Health and Human Services*, Case 19-60226, U.S. Fifth Circuit, January 14, 2021]

Genetic Testing Lab Pays $2.5 Million to Settle Kickback and False Claims Charges

Case: The feds accused a California-based molecular diagnostics firm of working with a marketing firm to carry out a scheme to falsely bill Medicare for medically unnecessary genetic tests performed on patients of 76 nursing homes generated via paid referrals. Rather than risk a trial, the firm agreed to settle the case for $2,538,000.

Significance: The DOJ claims that the lab agreed to pay the marketing firm a cut on the Medicare reimbursement for every genetic test referred by the firm's clients. If Medicare didn't pay for the test, the firm didn't get the fee. The firm then teamed up with a Wisconsin nursing homes owner and operator to identify Medicare patients the firm could approach to obtain buccal cell samples that could be sent to the lab for genetic testing. In subsequently billing Medicare for the tests, the lab added False Claims Act violations to its kickback offenses. For its part, the nursing home operator has agreed to pay $1 million to settle claims arising from its role in the scheme.

DME Company Must Pay $762K for Retaliating against Whistleblower

Case: A key account manager (KAM) filed a *qui tam* lawsuit against the medical device company that employer her for allegedly accepting kickbacks from a leading client. When the client found out that it was named as a defendant in the case, it demanded that the company take the KAM off its account. The company not only agreed to the request but also put the KAM on indefinite paid administrative leave and assigned her to less favorable accounts when she returned. The KAM claimed retaliation. The jury agreed and awarded her $762,525 in damages. The company appealed but to no avail.

Significance: The *False Claims Act* bans employers from discriminating against employees "because of" their protected conduct. As is often the case in retaliation cases, the key question was whether the company took unfavorable action against the KAM "because" she filed the whistleblower lawsuit. Courts are split over what "because of" means. In some courts,

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to prove causation the whistleblower need only show that the lawsuit was just one factor. Other courts impose a stricter standard and require the whistleblower to prove that the protected action was the "but for" or motivating cause of the action. Addressing the issue for the first time, the U.S. Court of Appeals for the Third Circuit opted for the "but for" test. But it also concluded that the KAM produced enough evidence to meet this more stringent test and upheld the jury award.

[*Lestage v. Coloplast Corp.*, 2020 U.S. App. LEXIS 38366, 982 F.3d 37]

CLIA Lab Subject to HIPAA Not Necessarily Exempt from State Medical Privacy Law

Case: Plasma donors filed a class action claiming that a plasma donation company's use of a donor-identification system based on a donor's fingerprints and biometric information without consent violated Illinois medical privacy laws. The company, which happened to be a CLIA lab, claimed that the state law didn't apply citing the definition of biometric identifiers as excluding "information collected, used, or stored for health care treatment, payment, or operations under" the federal HIPAA law. The exclusion applied, the company argued, because as a CLIA lab, it might have to disclose lab testing results of a donor subject to HIPAA. But the Illinois federal court would let the company use the defense.

Significance: The defense failed not because the application of HIPAA would have exempted the company from the state law but because it didn't adequately explain the connection between collecting a biometric template from donors on the front end and how that template is "collected, used, or stored for health care treatment, payment, or operations under [HIPAA]." The mere fact that the company was a lab subject to CLIA, which in turn made it subject to HIPAA wasn't enough to establish such a connection, the court explained.

[*Crumpton v. Octapharma Plasma, Inc.*, 2021 U.S. Dist. LEXIS 9520]

Employee Can't Blame Positive Marijuana Test on Testing Lab's Negligence

Case: An oil and gas worker was reassigned to a less desirable warehouse position after his hair follicle test came back positive for marijuana. The worker insisted he was clean—his urine drug and alcohol breathalyzer tests both came back negative—and blamed the positive result on the negligence of the lab in collecting and testing the hair sample. The lab contended that the case was baseless. The Louisiana court agreed and dismissed the negligence claims without a trial.

Significance: During the summary judgment phase, the plaintiff doesn't have to prove the case but must show that it's legally valid to win the chance to go to trial. The worker in this case didn't do that. The first problem with his negligence case against the testing lab is that it didn't

actually collect the hair sample. Under the employer's testing regime, a separate lab collects the samples and sends them to the testing lab for analysis. Nor was there any evidence that the lab was negligent in testing the sample, the court concluded, citing the written statement from the lab's senior analytical chemist for mass spectrometry describing the lab's utilization of a two-part, FDA-approved hair sample drug test for marijuana detection.

[*Bass v. DISA Global Sols., Inc.*, 2020 La. App. LEXIS 1943, 2020 0071 (La.App. 1 Cir. 12/30/20), 2020 WL 7770253]

Lab Safety: Statistics Suggest OSHA Has Been Lax in Enforcing Workplace COVID-19 Safety

As COVID-19 cases surge, going to work has become a risky proposition, especially for employees of labs, hospitals and other health care facilities. The Occupational Safety and Health Administration (OSHA) is the federal agency charged with enforcing workplace safety rules and holding employers accountable for taking measures to protect workers from exposure to COVID-19 infection risks. Many have questioned whether OSHA has been doing enough to meet this mandate. In response to the criticism, the agency released a statistical report documenting its COVID-19 enforcement efforts starting with the beginning of the pandemic and running through Dec, 31, 2020. While designed to reassure stakeholders that the rules are (or at least were) being vigorously enforced, the report actually suggests otherwise.

OSHA Liability for COVID-19 Violations

Nobody disputes that under OSHA, labs and other employers have a duty to protect workers from risk of COVID-19 infection. What may be less clear, is the source of that duty. Neither the *Occupational Safety and Health Act* (Act) nor the regulations say anything about COVID-19 or, with a few exceptions, infectious illnesses in general. But then again, they also leave out other hazards. Notable omissions include workplace violence, musculoskeletal and ergonomic injuries, cold and heat stress, to name just a few. But in spite of all this, OSHA inspectors still hand out citations and fines against employers that fail to guard against these workplace hazards.

How can OSHA do this? **Answer:** OSHA's authority to issue fines for failing to control hazards not specifically mentioned in the Act or regulations comes from Section 5(a)(1) of the Act, aka, the "general duty clause," which requires employers to furnish a workplace that's "free from recognized hazards" likely to cause death or serious physical harm to a

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Lab Safety: Statistics Suggest OSHA Has Been Lax in Enforcing Workplace COVID-19 Safety, *from page 7*

worker. And coronavirus is clearly a "recognized hazard," especially in COVID-19 testing labs and other healthcare settings.

In addition, inspectors looking into coronavirus compliance can also cite employers for violations of other OSHA rules that are expressly spelled out, such as requirements pertaining to personal protective equipment (PPE), respiratory protection and safety training.

How Big Are OSHA Penalties?

OSHA penalties vary in size, depending on how the inspector that hands them out characterize the violation. The agency indexes penalties every year. Here were the penalty amounts during the pandemic year of 2020 covered in the OSHA report:

2020 OSHA Penalty Amounts

Type of Violation	Minimum Penalty	Maximum Penalty
Serious	$964 per violation	$13,494 per violation
Other-Than-Serious	$0 per violation	$13,494 per violation
Willful or Repeated	$9,639 per violation	$134,494 per violation
Failure to Abate (i.e., fix a cited violation)	NA	$13,494 per day up to maximum of 30 days
Posting Requirements	$0 per violation	$13,494 per violation

2020 OSHA COVID-19 Enforcement by the Numbers

According to the report, in 2020, OSHA carried out 300 COVID-19 inspections. To put those numbers into context, the agency performs an average of 32,000 total inspections per year. You don't need us to do the math to determine how much of a priority COVID-19 was for inspection over the year.

The other key number in the report is $3,930,381, the **total** amount in penalties that OSHA inspectors proposed against employers cited for COVID-19 violations. The word "proposed" denotes that employers cited for OSHA violations have the right to appeal the proposed penalty amount. In other words, cited employers who appealed might have received a smaller penalty or even no penalty at all.

The report also lists the types of violations for which employers were cited, including failure to:

- Comply with the general duty clause requirement to provide a workplace free from recognized hazards;
- Implement a written respiratory protection program;
- Provide a medical evaluation, respirator fit test, training on proper respirator use and PPE;
- Report a workplace injury, illness or fatality; and
- Record an injury or illness on OSHA 300 logs and other recordkeeping forms.

What the report doesn't address is the size of the **individual** penalties handed out. And to the extent OSHA is trying to make a point about how tough it's been in enforcing coronavirus safety rules, this omission might well have been deliberate. Based on incremental reports listing fines against employers over a weekly period, we can discern that the highest proposed fine against an employer for a COVID-19 violation was a mere $26,988. The vast majority of proposed fines were at or below the $13,494 maximum for a serious violation.

One final note: The report includes only enforcement activity carried out by federal OSHA. Twenty-two states, including California, have their own state OSHA equivalent programs imposing requirements that are typically stricter than federal standards.

Takeaway

Although the fine totals sound impressive, the numbers support the contention that OSHA has been less than vigorous in its efforts to enforce COVID-19-related safety rules in the workplace. Inspections have been relatively few in number and the penalty amounts modest, particularly as compared to fines the agency hands out for fall protection, Hazcom, confined spaces, lockout, machine guarding and other common violations.

Of course, the report covers enforcement activity during the last administration. Now that OSHA is under new management, COVID-19 inspection pressure is likely to intensify in 2021.

TOOL MODEL SOCIAL DISTANCING POLICY

As the pandemic drags on, labs and other essential businesses that remain open must be scrupulous to ensure employees maintain social distancing both at and away from the workplace. Here's a Model Policy you can adapt to accomplish that objective in accordance with your specific circumstances and the terms of the latest public health guidelines in effect in your state or city.

SOCIAL DISTANCING POLICY FOR LAB EMPLOYEES

1. PURPOSE

We want to express our gratitude and appreciate to all personnel who come to work during these challenging times and assure you that XYZ Laboratories is 100 percent committed to ensuring you a health and safety work environment and to implementing all necessary measures to protect you against the risk of infection in accordance with CDC and other public health guidance and government emergency orders (referred to collectively as "CDC guidelines"). One of the things the Company is doing to deliver on that commitment is to implement this Social Distancing Policy.

2. DEFINITION OF SOCIAL DISTANCING

"Social distancing" means maintaining at least 6 feet of physical separation between other persons at all times whenever possible.

3. IMPORTANCE OF SOCIAL DISTANCING

Social distancing is a vital and effective measure

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TOOL: Model Social Distancing Policy, *from page 9*

for preventing the spread of COVID-19 coronavirus infection. The reason social distancing is so important is because of how the virus spreads. It typically begins when an infected person makes physical contact with another person or coughs, sneezes or talks, which releases droplets from the mouth or nose that get into the air and drift into the mouth or nose of people nearby. People who are in close contact (within 6 feet) for a prolonged time (a minimum of between 10 and 30 minutes, depending on the distance) are at the greatest risk.

A person known to have COVID-19 can be physically isolated. The problem is that in as many as 1 in 3 cases, the infected person has no symptoms. You can never be sure whether somebody has COVID-19. As a result, social distancing is critically important to prevent infection, both at and away from the workplace.

4. SOCIAL DISTANCING MEASURES

In accordance with CDC guidelines, all XYZ Laboratories employees must comply with the following social distancing procedures and protocols while performing their job duties, whether at an XYZ Laboratories site or facility, in a vehicle or at an off-site location, as well as when they are off-duty and away from work:

4.1 Physical Distancing

All employees must maintain a minimum of 6 feet in distance from others at all times whenever possible, including when they are in workstations, washrooms, break rooms and other common rooms and areas and when walking.

4.2 Pathways

All employees must follow traffic flow directions, including one-way path markings, as well as barriers and instructions on signs.

4.3 Avoid Physical Contact

Do not shake hands or engage in any other physical contact with others where such contact can be avoided.

4.4 Work Schedules

XYZ Laboratories reserves the right to change employees' work schedule to minimize the number of employees in the workplace at any given time, subject to applicable employment standards laws. Such changes may involve any combination of alternate day work schedules and/or staggering of lunch and breaks and arrival and departure times.

4.5 Limits on Gatherings

In-person gatherings and meetings may include no more than [*insert number based on most current public health guidance in your jurisdiction*] persons for indoor gatherings and [insert number] persons for outdoor gatherings.

4.6 Limits on Visitors

All non-essential visitors are prohibited until further notice.

4.7 Mandatory Face Masks

Employees who cannot avoid close contact must wear a non-medical mask or face covering, unless they can provide documentation showing that they have a medical or other condition that makes it difficult or dangerous for them to do so.

5. OFF-DUTY CONDUCT & SELF-DISCLOSURE

To avoid COVID-19 exposure that may endanger co-workers and others in the workplace, employees must also follow social distancing protocols and wear a mask when they are away from work. Employees who violate CDC guidelines and the restrictions set forth in this Policy, regardless of the site of such conduct and whether it happens while employees are on-duty or off-duty must self-disclose this to their supervisors before reporting to work for their next shift. XYZ Laboratories reserves the right to require such individuals to self-isolate in accordance with CDC guidelines.

6. ENFORCEMENT

Failure to comply with this Policy, including but not limited to the off-duty conduct and self-reporting requirements of Section 5, may result in discipline up to and including termination in accordance with XYZ Laboratories progressive disciplinary procedures and the terms of applicable collective agreements. Employees must report any Policy violations they witness or become aware of to their supervisor

immediately. No employee will be subject to reprisal or retaliation of any kind for reporting Policy violations.

7. RIGHT TO REVISE POLICY

Because CDC guidelines change frequently as the COVID-19 situation evolves, XYZ Laboratories reserves the right to modify this Policy any time and at its sole discretion.

ACKNOWLEDGEMENT

I acknowledge that I have received, read and understood this Policy and agree to comply with all of its terms.

Printed Name _____

Signature _____

Date_____

Managing Staff: Disciplining Employees for Not Following COVID-19 Restrictions When They Are Off-Duty

PICTURE THIS

COVID-19 cases are surging. Your state or city is in full lockdown mode. That means, among other things, that outdoor gatherings of more than 50 people aren't allowed. So, it disturbs you to turn on the news and see hundreds of people crowding together to demonstrate right in the middle of downtown. And then it gets personal. You recognize one of those demonstrators. She's one of your lab's employees! What the heck is she doing there?! And, gulp, you also notice that she's not wearing a mask! Now what? Can you discipline the employee for participating in the illegal demonstration and not wearing a mask?

Off-Duty Conduct, Employee Discipline and COVID-19

The statement that what employees do when they're away from work is none of your business is a myth. The truth is that off-duty conduct may be grounds for discipline when it does damage to a business, such as by hurting an employer's reputation, rendering the employee ineffective and/or making others unwilling to work with the employee. Justification for discipline is even greater for labs and other healthcare operations, particularly in times of pandemic.

The problem is that it's unclear how these standard rules for normal times would play out in the COVID-19 context. And that uncertainty will remain in place unless and until courts, arbitrators and tribunals begin deciding cases addressing whether an employer may discipline an employee for not following COVID public health guidelines while they're away from work.

Of course, labs could make a strong argument that partaking in a political demonstration without a mask during a pandemic would be grounds for discipline, especially since the demonstration violates current COVID-19 restrictions on public gatherings.

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Managing Staff: Disciplining Employees for Not Following COVID-19 Restrictions When They Are Off-Duty, *from page 11*

But there's no assurance that the lab would be able to sell that to a judge or arbitrator. Consider the potential problems in our political demonstration scenario:

- It would be hard to show that employee hurt the lab's reputation because of the unlikelihood that anybody watching reports of the demonstration would have noticed the employee among the crowd, let alone recognize that she works for your lab;
- Being mask-less at the demonstration would clearly enhance her risks of getting COVID-19, the results of which would be to undermine the employee's effectiveness, but it would be almost impossible to prove that participating in the demonstration actually caused her infection; and
- While other lab workers might be unwilling to work with the employee if they knew she was at a public demonstration without wearing a mask, how likely would they be to actually learn that she engaged in this conduct?

Bottom Line: Under current case law, an employee's failure to follow COVID-19 protocols while off-duty may not, by itself, be sufficient grounds for discipline. There may also be constitutional barriers to discipline, depending on what the employee was doing. Thus, for example, discipline for participating in a political demonstration—even an illegal one—could violate an employee's free speech rights; discipline for attending religious services or funerals could violate her religious rights.

Mandatory Self-Isolation

Still, while discipline may be tough to justify, taking part in a large demonstration without a mask in violation of current restrictions on public gatherings is clearly dangerous, even if it occurs while the employee is off-duty. After all, because COVID-19 cases are often asymptomatic, there's a pretty good chance that at least some of those demonstrators had the virus. And if the employee was in close contact with them, the employer not only can but probably should bar her from coming to work on Monday and require her to go into self-isolation immediately (unless it can effectively isolate her within the lab, such as by scheduling her for a shift when nobody else is on duty and/or making her work in an isolated office, room or work station).

However, the employer would have to treat mandatory self-isolation as a health and safety measure rather than a disciplinary action. In effect, the self-isolation would constitute unpaid leave rather than a suspension or even termination. Leave might even have to be paid depending on the labor standards requirements of the particular jurisdiction or the terms of leave policies if your lab provides paid leave when it's not legally required.

Implement On- and Off-Duty Social Distancing Policy to Protect Your Lab

Although the case law hasn't caught up, the fact is that during these times of pandemic, the things employees do when they're away from work do have health consequences for themselves and others at the workplace. That's why you should implement a policy requiring lab employees to follow social distancing, mask and other COVID public health guidelines not only at the workplace but also when they're off-site, even when they're off-duty. Like the Model Policy on page 9 in this issue of *Lab Compliance Advisor*, your policy should require employees to self-disclose any off-duty conduct that violates public health guidelines or your social distancing policies had it occurred at work to their supervisors before reporting to work for their next shift. Last but not least, require employees to report violations committed by others that they witness or know about and assure them that they will suffer no reprisals if they do so.

Compliance Briefing: How to Comply with the New HHS COVID-19 Test Data Reporting Rules,

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but the responding officers could tell that something was just not right. So, they gave the daughter a choice: go to the emergency room or go to jail. After initially choosing jail, the daughter changed her mind and went to the ER, where she was given a mental screening leading to a diagnosis of bipolar disorder.

The daughter sued the hospital for, among other things, deliberately fabricating the diagnosis so it could send her to a short-term mental facility affiliated with the hospital and bill federal healthcare programs for the cost. But instead of hiring an attorney, she filed what's called a *pro se* case, i.e., one in which litigants represent themselves. Individuals are normally allowed to do this when bringing a civil lawsuit for money damages. It may be that they don't have the money to hire a lawyer; or maybe they just think they understand the case better than anybody else.

The problem, as the whistleblower in the New Jersey case would learn the hard way, is that while the FCA allows private citizens to bring FCA *qui tam* whistleblower lawsuits, it doesn't allow them to do it on a *pro se* basis. And since the relator in this case didn't have an attorney, the federal district court tossed her FCA claims without a trial. She could have fixed the problem by hiring an attorney. Instead, she appealed, which turned out to be a waste of time and effort when the U.S. Appeals Court for the Third Circuit summarily upheld the lower court's ruling.

[*Ajjahnon v. St. Joseph's Univ. Med. Ctr.*, 2020 U.S. App. LEXIS 40459, 2020 WL 7694086]

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Takeaway: Relators Must Hire an Attorney

At first blush, it may seem incongruous to let individuals file qui tam *lawsuits on the government's behalf but not let them do so on a pro se basis. After all, whistleblowers are a tough lot willing to take on the establishment by themselves. But the rule, which has emerged from how federal courts have interpreted the FCA in actual cases, makes a lot of sense when you consider the reasons behind it.*

First, a qui tam *case isn't really about the relator but the federal government. Or, as courts phrase it, "the United States is the actual party in interest." The claim belongs to the government; the FCA merely allows the relator to assert it on the government's behalf. And, the thinking goes, if relators are going to avail themselves of that right, they owe it to the government and taxpayers to do it right. And that means hiring professional counsel and not bringing the case themselves.*

Equally, if not more compelling, is the fact that while the FCA gives a relator the "right to conduct the action" (31 U.S.C. § 3730(c)(3)), it includes no language enabling a relator to conduct the action without an attorney. And every circuit court that has addressed the issue has pointed to that omission in not allowing a relator to bring a pro se qui tam *lawsuit.*