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Compliance Alert: Take 15 Steps to Comply with New OSHA Emergency Health Care Worker Protection Requirements

During the Trump administration, the federal Occupational Safety and Health Administration (OSHA) came under heavy criticism for not doing enough to protect health care and other essential workers against risk of exposure to COVID-19. On his very first day in office, the new President pledged to rectify that situation. It took almost six months but on June 10, 2021, OSHA finally issued new OSHA requirements for frontline health care workers. Here's an overview of the new Emergency Temporary Standard (ETS) and the 15 things labs must do to comply with it.

Whom the ETS Covers

The ETS, which took effect on June 21, applies to settings where an employee provides healthcare services or healthcare support services, including labs, hospitals, nursing homes, assisted living facilities, emergency response, home healthcare and ambulatory facilities that treat confirmed or suspected COVID-19 patients. However, it doesn't cover:

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Kickbacks: LabCorp Faces Trial for Providing In-Office Phlebotomist Services to Doctors Taking Processing and Handling Fees from HDL

The Health Diagnostic Laboratory (HDL) and Singulex, Inc. scam in which physicians were paid process and handling fees for referrals of medically unnecessary blood tests remains the biggest and most notorious lab kickback scandal in history. And while the entities settled in 2015, the case remains highly radioactive to not only the HDL and Singulex principals but also the physicians on the receiving end of those illegal

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- Non-hospital ambulatory care settings where all non-employees are screened before entry and people with suspected or confirmed COVID-19 aren't allowed to enter;
- Well-defined hospital ambulatory care settings where all employees are fully vaccinated and all non-employees are screened before entry and people with suspected or confirmed COVID-19 aren't allowed permitted to enter; or
- Healthcare support services not performed in a healthcare setting, e.g., off-site laundry, off-site medical billing).

1. COVID-19 Plan

The ETS requires employers to create and implement a COVID-19 plan for each workplace. You can use a standard plan for all workplaces, as long as they're substantially similar. The plan must be in writing if there are more than 10 employees. Elements the plan must include:

- Designation of one or more persons who are knowledgeable in infection control principals and practices to act as workplace COVID-19 safety coordinator with authority to ensure plan compliance;
- Workplace-specific hazard assessment to identify COVID-19 hazards, carried out with the participation of non-managerial employees or their representatives;
- Ongoing plan monitoring; and
- Implementation of appropriate engineering controls, administrative/work controls and personal protective equipment (PPE) to eliminate or minimize identified hazards.

2. Patient Screening & Management Controls

In settings where direct patient care is provided, the employer must screen and triage all clients, patients, residents, delivery people and other visitors, as well as other non-employees entering the facility.

3. Standard and Transmission-Based Precautions

The ETS requires employers to implement policies and procedures to ensure compliance with the Standard and Transmission-Based Precautions set forth in the CDC's "Guidelines for Isolation Precautions."

4. Face Masks

Employers must provide, and ensure that employees wear, facemasks (defined as "a surgical, medical procedure, dental, or isolation mask that is FDA-cleared, authorized by an FDA EUA, or offered or distributed as described in an FDA enforcement policy") when they're indoors or in a vehicle with other people for work purposes. The employer must provide ample numbers of face masks and ensure that employees change them at

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least once a day or more often, as necessary. Exceptions: Face masks aren't required:

- When an employee is alone in a room;
- While an employee is eating and drinking at the workplace, as long as employees are at least 6 feet apart or separated by a physical barrier;
- When employees wear respiratory protection;
- When it's important to see an employee's mouth and clear plastic facemasks are too dangerous;
- When employees can't wear face masks due to medical conditions, religious beliefs or disabilities; or
- When the employer can show that use of a face mask would create a serious hazard to an employee.

5. Other PPE

When employees are exposed to or perform aerosol-generating procedures on a person with suspected or confirmed COVID–19, the employer must provide and ensure employees properly use a respirator, gloves, an isolation gown or protective clothing and eye protection. The ETS "encourages" employers to select elastomeric respirators or PAPRs instead of filtering facepiece respirators to prevent shortages and supply chain disruption.

6. Additional Precautions for Aerosol-Generating Procedures

When an aerosol-generating procedure is performed on a person with suspected or confirmed COVID–19, the employer must:

- Limit the number of employees present to only those essential for patient care and procedure support;
- Ensure that the procedure is performed in an existing airborne infection isolation room (AIIR), if one is available; and
- Clean and disinfect the surfaces and equipment in the room or area where the procedure was performed after it's done.

7. Social Distancing

Other than for momentary exposure when people are in movement, e.g., passing through aisles or hallways, employer must ensure that each employee is separated from other people by at least 6 feet when indoors unless the employer can demonstrate that such physical distancing isn't feasible for a specific activity (e.g., hands-on medical care).

8. Physical Barriers

The employer must install cleanable or disposable solid barriers, at each fixed work location outside of direct patient care areas (e.g., entryway/ lobby, check-in desks, triage, hospital pharmacy windows, bill payment)

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where employees aren't at least 6 feet apart, except where the employer can demonstrate it isn't feasible. The barrier must be located to block face-to-face pathways between individuals but can have a pass-through space at the bottom for objects.

9. Cleaning & Disinfection

The employer must follow CDC cleaning and disinfection guidelines and standards in patient care areas, resident rooms and for medical devices and equipment. In all other areas, the employer must:

- Clean high-touch surfaces and equipment at least once a day, following manufacturers' instructions for application of cleaners; and
- Follow the CDC's "Cleaning and Disinfecting Guidance" in any areas, materials and equipment that have likely been contaminated by a person who' COVID–19 positive within the last 24 hours;
- Provide alcohol-based hand rub that's at least 60% alcohol or provide readily accessible hand washing facilities.

10. Ventilation

Employers who own or control buildings or structures must ensure that the existing heating, ventilation, and air conditioning (HVAC) system(s) is used in accordance with the manufacturer's instructions and the system's design specifications and that air changes per hour are maximized. All air filters must be rated Minimum Efficiency Reporting Value (MERV) 13 or higher, if compatible with the HVAC system(s). If MERV–13 or higher filters aren't compatible, employers must use filters with the highest compatible filtering efficiency for the HVAC system(s). The ETS notes that this section doesn't require installation of new HVAC systems or AIIRs to replace or augment functioning systems.

11. Employee Screening, Contact Tracing & Removal

10.502(l)(1)(i)

Each employee must be screened before each work day and shift via by asking the employee to self-monitor before reporting to work or in-person screening conducted by the employer. If employers require COVID–19 testing for screening purposes, they must provide the test at no cost to the employee. The employer must require each employee to promptly notify the employer when the employee (referred to collectively as the "Criteria"):

- Is COVID–19 positive;
- Has been told by a licensed healthcare provider that they're suspected of having COVID–19; or
- Is experiencing COVID-19 symptoms.
- Upon being notified that a person who's been in the workplace is COVID-19 positive, the employer must, within 24 hours:

- Notify each employee who wasn't wearing a respirator and other required PPE who had close contact (defined as being within 6 feet for a cumulative total of 15 minutes or more over a 24-hour period during the person's potential period of transmission) with that person in the workplace;
- Notify all other employees who weren't wearing a respirator and other required PPE and worked in a well-defined portion of a workplace (e.g., a particular floor) in which that person was present during the potential transmission period.

Notification must include the date and time of contact but not any employee's name, contact information (e.g., phone number, email address), or occupation.

The employer must immediately remove any employee it knows meets the Criteria and provide him/her a COVID-19 polymerase chain reaction (PCR) test at no cost to the employee:

- If the test results are negative, the employee may return to work immediately; and
- If the test results are positive or the employee refuses to take the test, the employer must keep the employee removed until he/she meets the criteria for return.

The employer must keep the employee removed for 14 days but can offer to provide a free COVID-19 test to him/her at least five days after the exposure and, if the test is negative, allow him/her to return after 7 more days.

12. Mandatory Medical Removal Benefits

Employers with more than 10 employees must provide employees who are medically removed from work their normal pay and benefits up to $1,400 per week until they meet the requirements for returning to work. **Exception:** Employees who refuse to be COVID-19 tested don't get removal benefits.

13. Return to Work

The employer must follow CDC guidelines in determining when employees who are medically removed may return to work.

14. Paid Vaccination Leave.

The employer must provide employees "reasonable time and paid leave" (e.g., paid sick leave, administrative leave) for vaccination and to recover from any vaccination side effects.

15. Training

Employers must ensure each employee receives training in a language and at a literacy level the employee understands so that the employee

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comprehends disease transmission, tasks and situations in the workplace that could result in COVID-19 infection, and relevant policies and procedures. It must also ensure employees receive additional training when changes occur that affect the employee's risk of infection, if policies or procedures are changed, or when there's an indication that an employee hasn't acquired or retained the necessary understanding or skill.

Takeaway

At first glance, the ETS laundry list of required COVID-19 safeguards appears fairly extensive and intimidating. The good news is that many, if not most of these requirements are measures that are already mandatory under CDC and public health guidance, including screening, cleaning, disinfection, PPE, face masks, physical barriers. What is new—and fairly controversial—are the benefit provisions, which you'd normally expect to find in labor standards rather than OSHA laws.

TOOL MODEL COVID-19 WORKPLACE HAZARD ASSESSMENT POLICY

Among other things, the new OSHA Emergency Temporary Standard (ETS) requires labs and other covered employers to conduct a workplace hazard assessment to identify COVID-19 hazards. Here's a Model Policy you can adapt to comply with the new ETS rules.

WORKPLACE COVID-19 HAZARD ASSESSMENT POLICY

1. PURPOSE

To establish a cost-effective, workable, scalable, and flexible system to identify, assess and control workplace COVID-19 infection hazards at XYZ Laboratory workplaces in accordance with the requirements of the Occupational Health and Safety Act and associated Regulations, including but not limited to the Emergency Temporary Standard ("ETS"), as well as other applicable orders and guidelines from the government and public health agency ("Guidelines") requirements and standards.

2. DEFINITIONS

For purposes of this Policy:

"Administrative controls" means the provision, use, and scheduling of work activities and resources in the workplace, including planning, organizing, staffing, and coordinating, for the purpose of controlling COVID-19 risk;

"Competent" means possessing knowledge, experience, and training to perform a specific duty safely and effectively;

"Engineering controls" means the physical arrangement, design, or alteration of workstations, equipment, materials, production facilities, or other aspects of the physical work environment, for the purpose of controlling risk.

3. SCOPE

The intent of this Policy is to identify, assess, and control COVID-19 hazards that endanger the health and safety of not only workers but all persons present

at XYZ Laboratory facilities and work sites, including but not limited to clients, customers, contract workers and visitors.

4. RAC SYSTEM

XYZ Laboratory will use a 3-phase system to protect workers, visitors, and others from COVID-19 the hazards of the workplace based on the principles of RAC:

R ecognition, i.e., identifying COVID-19 hazards;

A ssessment, i.e., evaluating the urgency of and prioritizing hazards identified; and

C ontrol, i.e., selecting appropriate measures to eliminate or control identified hazards.

5. PHASE 1. COVID-19 HAZARD RECOGNITION

The objective of the Recognition phase of the RAC system is to identify all COVID-19 hazards and potential hazards in the workplace in accordance with the following principles:

- Hazard identification will be conducted before work begins at a work site;
- Hazard identification will be done by a competent person who is familiar with infection control and the ETS;
- Non-management workers at the work site will participate in hazard identification via the workplace Joint Health and Safety Committee ("JHSC") or Health and Safety Representative ("Representative"), or if no JHSC or Representative exists, direct participation;

After completion of hazard identification, a written report will be prepared listing an inventory of COVID-19 hazards by job classification.

6. PHASE 2. COVID-19 HAZARD ASSESSMENT

The objective of the Assessment phase is to analyze the COVID-19 hazards identified during the Recognition phase and determine urgency. Using the inventory of hazards created at the end of the Recognition phase, a competent person will assess the identified hazards by completing the COVID-19 Hazard Assessment Form (a copy of which is attached to this Policy as Attachment A) rating each job classification by level of exposure as:

- Very high;
- High;
- Medium; or
- Lower.

Such assessments will be based on COVID-19 risk factors, including:

- Physical distance of workers from co-workers, customers and other persons at the site between and/or employees and customers;
- Effectiveness of current ventilating, air circulation and HVAC systems;
- Operations requiring close contact, e.g., sharing of vehicles;
- Age, respiratory or immune disorders, or other chronic medical conditions or physical characteristics making persons at the site unusually susceptible to COVID-19 infection; and
- Availability of respirator masks and other necessary PPE.

7. PHASE 3. COVID-19 HAZARD CONTROL

XYZ Laboratory will ensure all reasonably practicable steps are taken to control COVID-19 hazards identified in Phase 1 on the basis of the assessment performed in Phase 2 in accordance with the following principles:

If reasonably practicable, XYZ Laboratory will eliminate COVID-19 hazards. Where total elimination is not reasonably practicable:

- Reasonably practicable engineering controls will be used to control the hazard;
- Administrative controls will be used where engineering controls are not reasonably practicable or as a supplement to engineering controls to minimize the COVID-19 hazard;
- Gloves, masks, aprons and other personal protective equipment will be used as a last resort or as a supplement to engineering and administrative controls.

8. REVIEW & EVALUATION

The following monitoring and review measures will be taken for as long as the COVID-19 pandemic lasts or until such time that COVID-19 infection no longer poses a significant risk:

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Model COVID-19 Workplace Hazard Assessment Policy, *from page 7*

8.1 Review of Hazard Identification & Assessment

COVID-19 hazard identification and assessment required by Phases 1 and 2 will be repeated:

- At reasonable intervals to prevent the development of unsafe and unhealthy work conditions;
- When a new work process is introduced;
- When a work process or operation changes;
- Before construction of significant additions or alterations to the work site; and/or
- In response to changes to Guidelines.

8.2 Review of Safety Controls

The effectiveness of COVID-19 hazard controls will be reviewed:

- As part of monthly workplace inspections carried out;
- In response to circumstances suggesting that conditions have changed and that controls might no longer be effective, including but not limited to:
  - o The occurrence of injuries, illnesses, incidents, accidents, or near-misses;
  - o Complaints or concerns expressed by workers at the site, either directly or through their JHSC or Representative;
  - o After significant changes to the affected job or process's location, procedures, required equipment, etc.; and
  - o In response to changes to the Guidelines, ETS or other regulatory requirements.

TOOL MODEL COVID-19 HAZARD ASSESSMENT FORM

XYZ Laboratory COVID-19 Hazard Assessment Form

PART A: SHOULD THE WORKER BE ALLOWED AT THE WORK SITE?	
1. Does worker have fever, cough, shortness of breath, trouble breathing, sore throat or runny nose?	
[ ] No—Go to Question 2	[ ] Yes—Worker must be at home in self-isolation for 14 days after symptoms completely disappear
2. Has worker traveled outside the state within last 14 days?	
[ ] No—Go to Question 3	[ ] Yes—Worker must be at home in self-isolation for 14 days
3. Has worker tested positive for COVID-19?	
[ ] No—Go to Question 4	[ ] Yes—Worker must be at home in self-isolation for 14 days
4. Has worker had any known exposure to COVID-19, e.g., near infected person without PPE?	
[ ] No—Go to Question 5	[ ] Yes—Worker must be at home in self-isolation for 14 days
5. Does worker perform an essential service?	
[ ] No—Go to Question 6	[ ] Yes—Worker must undergo risk assessment under Part B
6. Can worker perform the job remotely?	
[ ] No—Go to Question 7	[ ] Yes—Company must implement work-at-home agreement for worker
7. Do work schedules + physical work environment ensure social distancing of at least 6 feet apart?	
[ ] No—Perform risk assessment under Part B	[ ] Yes—Company must develop physical distancing operational plan that works for its business

PART B: PERFORM COVID-19 RISK ASSESSMENT	
Complete the following risk assessment to identify: *How workers may be exposed to COVID-19, e.g., via contact with co-workers, customers + general public *Workers' individual risk factors, e.g., age, chronic medical conditions, pregnancy *Controls necessary to eliminate or minimize risk	
Job-Related Risk Levels for COVID-19	
Exposure Risk Level	**Description of Jobs**
Very High	Frequent + direct exposure to COVID-19, e.g., health care workers + lab personnel working with COVID-19 patients
High	Indirect exposure to COVID-19, e.g., ambulance staff or hospital workers entering COVID-19 patients' rooms
Medium	Frequent/close contact (within 6 feet) with potentially infected people who aren't COVID-19 patients, e.g., at airports or retail stores
Lower	No required frequent/close contact with people who may be infected

PART C: SELECT CONTROL MEASURES (in order of preference)
[ ] Eliminate hazard: Remove task, equipment, chemical or action that causes hazard, e.g., having workers work remotely
[ ] Substitute: Replace hazardous work process, substance, tool or equipment with a less hazardous one
[ ] Eliminate hazard: Remove task, equipment, chemical or action that causes hazard, e.g., having workers work remotely
[ ] Engineering controls: Design work site, equipment or process to eliminate, minimize or isolate the hazard, e.g., ventilation or use of physical barriers
[ ] Administrative controls: Safe work procedures, training and other methods of limiting hazard by controlling how work is done, e.g., social distancing, requiring frequent hand washing, staggering work shifts to minimize number of workers present at any time
[ ] PPE: Respirators, gloves, aprons + other protective equipment required based on exposure risk level

PART D. IMPLEMENT HAZARD CONTROLS	
Identified Hazard	**Control Method**

PART E: MONITOR EFFECTIVENESS OF CONTROL MEASURES
[ ] Create a plan to monitor that each control measure is working, e.g., safety inspection checklist
[ ] Correct measures found not to be working effectively
[ ] Seek JHSC or worker input in monitoring and taking corrective action

Name: _____

Title: _____

Date of Completion: _____

Labs IN COURT

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

Rhode Island Lab Settles Urine Drug Test False Claims Allegations for $650K

Case: The feds sued a Rhode Island doctor and the lab affiliates he owns for submitting tens of thousands of claims to Medicare and Medicaid for high-complexity urine drug screening tests that they did not and could not perform. According to the complaint, the doctor's urgent care center first ran moderate complexity drug screens on the urine samples. Then, since the lab didn't have the equipment necessary to perform high-complexity screen, the specimens were sent to an outside confirmation lab to obtain high-complexity results. Both the center and the outside lab then billed Medicare or Medicaid for high-complexity testing on the same specimen. Rather than risk a trial, the defendants have agreed to settle the claims for $650,000.

Significance: The billing was carried out by a local billing firm owned by the doctor's wife. In 2018, Rhode Island revoked the firm's registration to carry out business in the state.

California Pulmonologist Shells Out Over $200K to Settle Kickback Charges

Case: The former CEO of a California hospital filed a whistleblower suit accusing the hospital and at least two of its affiliates of hiring a pulmonologist at above fair market compensation to serve as medical director in exchange for patient referrals in violation of the Anti-Kickback Statute and Stark Law. Rather than risk a trial, the medical director agreed to pay $215,288 to settle the charges, $42,529 of which will go to the whistleblower.

Significance: This is the recent in a long line of cases targeting providers for paying excessive compensation to medical directors in an illegal bid to buy referrals. The hospital defendants named in the original whistleblower lawsuit settled in 2018 at a hefty $8.1 million price tag. The government's decision to intervene in the case likely exerted enormous pressure on the defendants to settle.

Texas Provider Pays $214K for Violating Federal COVID-19 Workplace Protocols

Case: In what appears to be a first, the Texas parent of an Iowa nursing home has agreed to repay $214,200 in federal monies for not following COVID-19 safety protocols during an outbreak at the facility from April through July 2020. Among other things, the nursing home didn't properly screen employees or require them to wear personal protective equipment. According to newspaper reports, three employees exhibiting COVID-19 symptoms and who subsequently tested positive for the virus were allowed to come to work and be near vulnerable residents, 11 of whom died during the outbreak.

Significance: The relatively small settlement award belies the importance of this case in that it represents the first settlement with a

health care provider for violating the COVID-19 workplace safety protocols during the pandemic. Labs that billed Medicare during the pandemic knowing that they were out of compliance with COVID-19 safety rules run the risk of liability under the False Claims Act. Notably, however, the settlement is based not on FCA liability but on "restitution," which is typically used to describe repayment of money received by mistake. It's also worth noting that the company in this case cooperated in the investigation, which is a highly advisable strategy if your lab comes under investigative scrutiny. In the meantime, continue to follow the screening, PPE and other safety rules scrupulously.

University of Miami Settles Lab Testing False Claim Charges for $22 Million

Case: In this particular case, "The U" of the University of Miami might have stood for unnecessary, as in medically unnecessary lab tests billed to Medicare by the UM's lab and off campus hospital-based facilities. The $22 million that the UM has agreed to fork over settles a trio of whistleblower lawsuits filed in 2013 and 2014, alleging that UM and its affiliates:

- Converted multiple physician offices to Off-Campus Hospital Facilities so it could bill Medicare for higher rates and without providing beneficiaries the required notice;
- Used its electronic ordering system to automatically prompt physicians to order multiple medically unnecessary tests for kidney transplant patients
- Submitted inflated claims for reimbursement for pre-transplant lab testing done by an affiliate that the affiliate should have billed for directly and then using the Medicare payments to pay the affiliate kickbacks for referring surgical patients.

Significance: The first takeaway of the settlement is to emphasize the importance of ensuring compliance with the Off-Campus billing of Medicare patients notice requirements. Such requirements count as conditions of payment and not complying with them can turn the claim into a false claim. The other moral of the UM story is that "standing" orders remain highly risky and are allowed only when strictly tailored to each patient's individual circumstances and needs.

Florida Telemarketers Indicted for $47 Million Genetic Test Fraud Scheme

Case: A federal grand jury indicted three telemarketing company owners for a smorgasbord of fraud, kickback and money laundering violations that allegedly cost Medicare $47 million medically unnecessary genetic tests. Following what has become a familiar pattern, the schemers ran a telemarketing campaign designed to get Medicare beneficiaries to undergo genetic cancer screening, regardless of their medical need. They

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Labs in Court, *from page 11*

then recruited a network of physicians who were willing to order the tests without seeing the patients in exchange for kickbacks. Those orders were then sold to the labs that performed the tests and sent the bill to Medicare.

Significance: Telemarketing schemes were just starting to penetrate the radar of federal enforcers before the pandemic hit. As utilization of telemedicine has increased, so has the level of enforcement scrutiny and activity, the culmination of which was last year's Operation Rubberstamp, a massive federal takedown. While not specifically its focus, genetic testing labs often play a key role in telemarketing fraud cases, as in this most recent indictment.

Kickbacks: LabCorp Faces Trial for Providing In-Office Phlebotomist Services to Doctors Taking Processing and Handling Fees from HDL, *from page 1*

processing and handling fees. The fallout has even extended to other testing labs that allegedly went about their business even though they were aware of what was going on. One of the biggest targets has been LabCorp, which a federal court has now ruled must stand trial for False Claims Act (FCA) violations stemming from its highly indirect and peripheral role in the scandal.

The South Carolina Whistleblower Case

The whistleblowers contend that LabCorp technicians stationed inside the offices of doctors taking illegal processing fees from HDL and Singulex were aware of the kickback arrangement but continued to draw blood from patients knowing that the specimens would be referred to HDL and Singulex for tests that would be subsequently billed to Medicare. Because those tests were the product of an illegal kickback, billing for them amounted to making a false claim under the FCA.

The case has been going on for years. The government has declined to intervene. And the South Carolina federal district court has dismissed three of the four broad sets of claims. But one group of claims has survived, namely, those related to whether the lab giant conspired in false claims made by HDL and Singulex and submitted false claims of its own. The newest ruling is on LabCorp's motion for summary judgment, i.e., dismissal without trial, on those claims. The court denied the motion, giving the relators an opportunity to prove the charges at trial.

Issue 1: Is LabCorp Liable for False Claims of HDL and Singulex?

The FCA imposes liability on "any person who knowingly . . . causes to be presented, a false or fraudulent claim for payment or approval" (Section 3729(a)(1)(A)). A person doesn't have to be the one that actually submits

the claim to be liable. Liability extends to claims that are rendered false by one party, but submitted to the government by another. The relators claimed that LabCorp had crossed the line and was liable for the false claims submitted by HDL and Singulex in connection with the blood draws of its in-office phlebotomists for the doctors receiving the processing and handling fees. To rule on this issue, the court focused on two parts of Section 3729(a)(1)(A)).

Did LabCorp Act "Knowingly"? The FCA defines "knowingly" as actual knowledge or acting in deliberate ignorance or in reckless disregard of the truth or falsity of the information. It doesn't require that the person have a specific intent to defraud. In deciding a summary judgment motion, courts look at the record in the light most favorable to the party being targeted for dismissal, in this case, the relators. Seen from this perspective, the court ruled that there were "disputes of material fact as to whether LabCorp acted in reckless disregard to the falsity of the information" presented in billing for the tests. Specifically, there was evidence showing that LabCorp was aware that its phlebotomists had been drawing blood for doctors who were "getting paid by HDL" and "that HDL calls the fee a 'process and handling fee.'" Later, it anonymously asked the OIG to issue a Special Fraud Alert identifying HDL's payment of processing and handling fees as a potential violation of the Antikickback Statute (AKS).

Did LabCorp "Cause" a False Claim to Be Presented? The FCA doesn't specifically define what it means to "cause" a false claim to be presented. The standard courts use is whether the person was "a substantial factor" in the claim's being presented and whether such presentation was foreseeable. The court had no trouble finding that it was foreseeable to LabCorp that HDL and Singulex would present claims to Medicare for the illegally referred tests. And the fact that its phlebotomists were drawing blood for the tests was also a "substantial factor."

Issue 2: Did LabCorp Submit False Claims of Its Own?

Section 3729(a)(1)(A) of the FCA imposes liability on a person who "knowingly presents. . . . a false or fraudulent claim for payment." The relators claimed that LabCorp itself paid kickbacks to the referring physicians by having its phlebotomist provide "courtesy draws," free blood draws to the doctors it knew were receiving kickbacks from HDL and Singulex to induce referrals to LabCorp. By then billing Medicare for tests done on those specimens, it submitted false claims. The court ruled that a jury could rule either way on whether courtesy draws crossed the line. As a result, it denied summary judgment on the claim.

Issue 3: Did LabCorp Conspire with HDL and Singulex to Submit False Claims?

Having found that there were genuine, trial-worthy disputes over whether the same was true on the question of whether LabCorp had knowingly

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Kickbacks: LabCorp Faces Trial for Providing In-Office Phlebotomist Services to Doctors Taking Processing and Handling Fees from HDL, *from page 13*

presented, or caused to be presented a false or fraudulent claim for payment under Section 3729(a)(1)(A), the remaining issue was whether it had also conspired with HDL and Singulex to commit such violations (in violation of the Section 3729(a)(1)(C) ban on conspiring to violate subparagraph (A)).

Unfortunately for LabCorp, the court said there was. Essentially, the same evidence showing that LabCorp knew what was going on but allowed its phlebotomists to continue drawing blood for physicians on the HDL and Singulex dole was enough to raise a trialable issue on conspiracy.

United States ex. rel. Lutz v. Lab. Corp. of Am. Holdings, 2021 U.S. Dist. LEXIS 112832, 2021 WL 2457693

Takeaway

Denial of summary judgment isn't a ruling on the merits. The relators will still have to prove their claims. And holding LabCorp liable for participating in the FCA offenses committed by HDL and Singulex will be anything but easy.

One key piece of evidence that wasn't enough to secure summary judgment but may be significant in defending the charges at trial is that after its LabCorp's compliance department investigated and became aware that in-office phlebotomists were drawing blood for doctors who were paid processing and handling fees by HDL and Singulex, certain LabCorp divisions stopped drawing blood for testing by those labs, required doctors to certify that they weren't receiving processing and handling fees, or instituted a $5 draw fee on the doctor. The key question is whether those actions were too little, too late, and why they weren't implemented across all LabCorp divisions.