

June 2020

IN THIS ISSUE

COMPLIANCE PERSPECTIVES:

How to Create a COVID-19 Exposure Control Plan **1**

BRIEF YOUR CEO:

The 18 Things You Can Do for COVID-19 that You Can't Do for Other Testing **1**

TOOL:

Model COVID-19 exposure control plan **5**

QUIZ:

Can Lab Lease Space for COVID-19 Testing to Referring Physician at Below-Market Rent? **10**

LABS IN COURT:

A roundup of recent cases and enforcement actions involving the diagnostics industry **12**

WHISTLEBLOWERS:

Lab to Pay Up to \$43 Million After Disregarding Employee's False Billing Concerns **14**

MEDICARE REIMBURSEMENT: CMS

Waivers Expand COVID-19 Testing Coverage Rules **15**

Compliance Perspectives: How to Create a COVID-19 Exposure Control Plan

For as long as COVID-19 remains a threat, businesses—both essential and nonessential—won't be allowed to re-open and remain open unless they implement a plan to control workplace infection risks. While infection control is nothing new for labs, the challenges posed by COVID-19 are unprecedented and unique and you probably won't find any great templates in your current policy folders and binders. As a result, you'll need to build your plan from the ground up. Here's a step-by-step strategy and Model COVID-19 Exposure Control Plan containing the necessary elements that you can use to accomplish that objective.

The Exposure Control Plan & Why You Need It

An exposure control plan is a set of measures to protect workers, patients, contractors, visitors and other people at your workplace against exposure to COVID-19 infection and

Continued on page 2

Brief Your CEO: The 18 Things You Can Do for COVID-19 that You Can't Do for Other Testing

Blanket Waivers relaxing kickback law restrictions standing in the way of desperately needed COVID-19 continue to play a crucial role in the federal government's response to the Public Health Emergency (PHE). As lab compliance officer, you need to make your officers aware of these Blanket Waivers and the potential business and testing opportunities they create for your lab. Here's a list of the talking points to cover in your CEO briefing.

Section 1135 Blanket Waivers

First, set the legal context for the CEO by explaining that during a PHE, CMS has discretion to not impose penalties on remuneration arrangements that would normally violate kickback and other anti-fraud laws. On March 30, 2020, the

Continued on page 16

■ Compliance Perspectives: How to Create a COVID-19 Exposure Control Plan, from page 1

ensure compliance with your obligations under OSHA laws, CDC and other public health guidelines.

Best Practice: Designate the lab manager or another competent individual who understands the OSHA laws and public health guidelines to serve as COVID-19 coordinator responsible for creating and implementing the plan. Although the COVID-19 exposure control plan is something novel, you can base it on your current OSHA policy templates, starting with a statement describing the plan's purposes (Plan, Sec. 1) and an allocation of roles and responsibilities (including management, the COVID-19 coordinator, supervisors and workers) (Plan, Sec. 2).

The 9 Key Safety Measures

The heart of the COVID-19 exposure control plan are its nine sets of safety measures.

1. COVID-19 Hazard Assessment

As with any other health and safety hazard, the starting point is to identify and assess the COVID-19 hazards at your lab. While no workplace is exempt from infection risks, the nature and degree of risk does vary from workplace to workplace. OSHA guidelines recommend basing the COVID-19 hazard assessment on job classification and ranking exposure level as Very High, High, Medium and Low considering the following COVID-19 risk factors:

- ▶ Physical distance of workers from co-workers, patients and other persons at the site;
- ▶ 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.
- ▶ Labs would likely fall into the Very High or High classification, particularly if they perform testing on samples of patients who have or are suspected of having COVID-19 (Plan, Sec. 3.1).

2. COVID-19 Field Level Hazard Assessment

In addition to the job classification assessment, a competent worker or supervisor at the lab should carry out a field level assessment before the shift to verify that the required safety measures are in place and immediately notify the person in charge of safety if something is amiss. Work shouldn't begin until the field assessment comes back clean or the cited problems are properly corrected (Plan, Sec. 3.2).

LCA

Glenn S. Demby,
Executive Editor

Barbara Manning Grimm,
Managing Editor

Jim Pearmain,
General Manager

Andrea Stowe,
Business Development

Pete Stowe,
Managing Partner

Mark T. Ziebarth,
Publisher

Notice: It is a violation of federal copyright law to reproduce all or part of this publication or its contents by any means. The Copyright Act imposes liability of up to \$150,000 per issue for such infringement. Information concerning illicit duplication will be gratefully received. To ensure compliance with all copyright regulations or to acquire a license for multi-subscriber distribution within a company or for permission to republish, please contact G2 Intelligence's corporate licensing department at myra@plainlanguagemedia.com or by phone at 888-729-2315. Reporting on commercial products herein is to inform readers only and does not constitute an endorsement.

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.

3. COVID-19 Safety Controls

The next phase of COVID-19 exposure control is to select measures to address identified infection hazards based on the findings of the job classification exposure assessment following the standard “hierarchy of controls,” i.e.:

- ▶ Totally eliminating the hazard if reasonably practicable, e.g., ceasing all operations requiring workers to have close contact;
- ▶ If elimination isn't reasonably practicable, using engineering controls like air-circulating and ventilating systems or physical partitions, to minimize hazards;
- ▶ Using safe work procedures and other administrative controls affecting how hazardous operations are carried out instead of or in combination with engineering controls to minimize exposure; and
- ▶ As a last resort where COVID-19 hazards can't be eliminated via engineering and administrative controls, requiring exposed lab workers to use PPE.

4. Social Distancing Measures

Labs must ensure that people at the workplace maintain the required 6 feet of separation from each other. The exposure control plan should describe all the things you're going to do to meet that massive challenge, e.g., physical workplace configuration, occupancy limits, bans on large meetings or gatherings, etc. (Plan, Sec. 5).

5. Medical Screening

Public health agencies, the EEOC, privacy commissions and other regulators have reluctantly given the green light for employers to medically screen workers and others seeking entrance to the facility for COVID-19 symptoms as long as screening measures are safe, fair, consistent, nondiscriminatory and as minimally privacy invasive as possible. So, make sure your exposure control plan explains your screening measures and the safeguards taken to keep them within the legal limits (Plan, Sec. 6). (See, “How to Create a Legally Sound Medical Screening Policy,” [LCA, April 27, 2020](#)).

6. Self-Isolation & Quarantine Measures

Explain the policies and procedures you'll use to bar employees (or others) who test positive for, exhibit symptoms of or are at otherwise at high risk of infection due to travel or direct and recent contact with a person that has COVID-19 from entering or remaining in the lab. Such procedures should also provide for removal, transport, communication and ultimately return to work of workers in self-isolation (Plan, Sec. 7).

7. Sanitation & Infection Control Measures

Describe the sanitary, cleaning and disinfection measures you'll take to

Continued on page 4

■ Compliance Perspectives: How to Create a COVID-19 Exposure Control Plan, *from page 3*

minimize COVID-19 infection risk, which at a minimum should include:

- ▶ Frequent and regular cleaning and disinfection of surfaces, equipment, door knobs, sinks, handles, keyboards, light switches and other touch points with EPA-approved products;
- ▶ Keeping wash rooms accessible, clean and amply supplied with soap, water and paper towels;
- ▶ Requiring workers to wash their hands frequently while at and immediately before leaving the lab;
- ▶ Posting notices demonstrating proper hand washing techniques in wash areas;
- ▶ Implementing safe work procedures for the handling of mail, packages, materials and goods entering and exiting the lab; and
- ▶ Requiring all workers to use “respiratory etiquette” and properly cover their mouth when they cough and sneeze.

(Plan, Sec. 8)

8. PPE

PPE is an absolute must, particularly where encounters between people closer than the prescribed social distancing 6 feet can't be avoided. In most workplaces, the vast majority of workers will fall into the Medium or Low exposure risk classifications requiring only a non-medical face mask and perhaps protective gloves. However, COVID-19 testing and other healthcare workers who treat or are near to COVID-19 patients will fall into the Very High and High risk classification requiring more elaborate PPE, including at a minimum, an N95 or other tight-fitting particulate respirator, gloves and an apron. Workers who make direct and close contact with COVID-19 patients or handle lab specimens will also need face masks, goggles, protective clothing and, in some cases, more elaborate respiratory protection, e.g., SCBA respirators (Plan, Sec. 9).

9. Safety Training & Instruction

All lab workers exposed to COVID-19 infection risks should receive safety information and training covering, at a minimum:

- ▶ How the virus spreads;
- ▶ The fact that there's currently no vaccine for COVID-19;
- ▶ How to reduce the risk of infection;
- ▶ The measures you've taken to minimize infection risks; and
- ▶ What workers should do and whom they should call if they believe they've been exposed. (Plan, Sec. 10)

Takeaway

The stakes are higher than you may realize. If you don't have the right exposure control plan in place, OSHA and public health inspectors can hit you with hefty fines and even shut you down. Failure to implement an effective plan also heightens the risk of liability and lawsuits by persons claiming to have contracted COVID-19 at your facility, including massive class action suits if you experience outbreaks or clusters of infections. 

TOOL

MODEL COVID-19 EXPOSURE CONTROL PLAN

Regulators have made it clear that workplaces, including labs, must implement written plans to control COVID-19 exposure risks at the

site. Here's a Model Plan template your lab can adapt that provides for the necessary protections.

COVID-19 EXPOSURE CONTROL PLAN TEMPLATE

1. PURPOSE

The purpose of this Plan is to prepare ABC Laboratories ("Labs") facilities and workplaces for re-opening and operating safely during the current COVID-19 pandemic by:

- ▶ Implementing measures to minimize the risk of infection to workers, patients and others present at Labs facilities;
- ▶ Establishing procedures for rapid response if individuals develop symptoms of illness while working or visiting Labs facilities;
- ▶ Maintaining high levels of sanitation and personal hygiene at the facilities at all times; and
- ▶ Ensuring compliance with all applicable Occupational Safety and Health requirements ("OSHA regulations") and the guidelines of the U.S. Centers for Disease Control and Prevention and other public health agency guidelines ("Guidelines").

2. ROLES & RESPONSIBILITIES

2.1 Employer

As employer, Labs is responsible for the overall implementation of the Plan, including by:

- ▶ Providing the leadership and resources necessary for the effective implementation of the Plan;
- ▶ Appointing a competent person to serve as COVID-19 Coordinator;
- ▶ Regularly reviewing the Plan;
- ▶ Monitoring the pandemic situation as it evolves to ensure that the Plan remains timely and in compliance with the most recent Guidelines; and
- ▶ Ensuring that workers receive the most current information about the pandemic and implementation of the Plan.

Continued on page 6

■ Model COVID-19 exposure control plan from page 5

2.2 COVID-19 Coordinator

The COVID-19 Coordinator is responsible for the day-to-day implementation of the Plan, including ensuring that:

- ▶ The COVID-19 workplace hazard assessment is carried out;
- ▶ Appropriate infection prevention and engineering and administrative controls are implemented to eliminate or minimize identified COVID-19 hazards;
- ▶ Medical screening and self-isolation procedures are carried out in a way that is fair, consistent, safe and as minimally privacy invasive as possible;
- ▶ All exposed workers receive and properly use the required PPE;
- ▶ All workers receive and follow their COVID-19 safety training and instruction;
- ▶ All patients, clients and visitors comply with Plan requirements; and
- ▶ All COVID-19 incidents are properly investigated and, if necessary, reported to OSHA, the Workers Compensation Board and other regulatory officials or entities.

2.3 Supervisors

Supervisors are responsible for:

- ▶ Developing and carrying out the safe work procedures necessary to implement the Plan;
- ▶ Ensuring the required COVID-19 field level hazard assessment is carried out before work begins;
- ▶ Delivering COVID-19 safety training and verifying that workers understand and are capable of following it on the job;
- ▶ Ensuring workers properly use, inspect, clean and store required PPE;
- ▶ Enforcing the requirements of the Plan and safe work procedures including, if necessary, via the imposition of discipline against workers that commit infractions; and
- ▶ Communicating with workers in self-isolation.

2.4 Workers

Workers are responsible for:

- ▶ Not coming to work if they feel ill;
- ▶ Complying with all ABC Company infection control and social distancing rules and COVID-19 safe work procedures;
- ▶ Properly using the required PPE; and
- ▶ Reporting any violations of this Plan to their supervisor or other appropriate Labs officials.

3. COVID-19 HAZARD ASSESSMENT

3.1 Job Classification Hazard Assessment

The COVID-19 Coordinator will create a written inventory of COVID-19 hazards by job classification and/or operations undertaken at the site. Using the inventory of identified hazards, the Coordinator will then perform

a COVID-19 hazard assessment by assigning each job classification one of the following levels of exposure:

- ▶ Very high;
- ▶ High;
- ▶ Medium; or
- ▶ Low.

In rating each job classification, the Coordinator will consider COVID-19 risk factors, including:

- ▶ Physical distance of workers from co-workers, patients and other persons at the site;
- ▶ 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.

3.2 Field Level Hazard Assessments

In addition and as a supplement to the above job hazard classification, a competent worker or supervisor at the site will perform a COVID-19 field level hazard assessment before work begins.

3.3 Review & Revision

All hazard assessments will be regularly reviewed and revised to ensure they reflect current site conditions and operations and comply with most recent OSHA regulations and Guidelines requirements.

4. COVID-19 SAFETY CONTROLS

Labs will implement appropriate safety measures to control the COVID-19 hazards identified during hazard assessment in accordance with the assigned level of exposure and following principles:

- ▶ Where reasonably practicable, Labs will take measures that completely eliminate the hazard, e.g., by letting susceptible workers work from home or eliminating operations requiring one or more worker to be in a vehicle at the same time;
- ▶ Where elimination is not reasonably practicable, Labs will implement engineering controls to minimize COVID-19 hazards, e.g., air-circulating and ventilating systems or physical partitions ensuring people at the lab remain separated;
- ▶ Labs will implement administrative controls, either in lieu of or in combination with engineering controls to minimize COVID-19 hazards, including the social distancing, medical screening, cleaning and disinfection and safety training protocols set forth below; and
- ▶ As a last resort where COVID-19 hazards cannot be eliminated or engineered away, Labs will ensure that all persons exposed to COVID-19 hazards have and properly use the appropriate PPE while present at the site, in accordance with Section 9 below.

5. SOCIAL DISTANCING

Labs will implement appropriate and reasonably practicable measures to ensure that persons at the workplace remain at least 6 feet apart. Such measures may include:

- ▶ Reviewing floor plans to determine how to maintain distance between work stations and separate workers from patients and visitors;

Continued on page 8

■ Model COVID-19 exposure control plan, from page 7

- ▶ Installing physical separation equipment such as Plexiglas screening;
- ▶ Posting signs warning occupants to maintain social distancing;
- ▶ Marking out designated traffic flow paths for high volume areas;
- ▶ Marking the distance of checkout areas;
- ▶ Limiting the number of persons allowed to enter the lab at any one time;
- ▶ Staggering work shifts to keep on-site staffing levels to the minimum possible;
- ▶ Staggering breaks, restricting access to and/or reducing seating capacity/density in reception areas, lunchrooms, meeting rooms and other gathering places;
- ▶ Creating an elevator usage plan limiting the number of people allowed in elevators at one time;
- ▶ Substituting virtual meetings for in-person meetings whenever possible
- ▶ Where in-person meetings can't be avoided, limiting them to the fewest participants possible and holding them in the biggest space available;
- ▶ Allowing employees not needed at the site work from home;
- ▶ Establishing and strictly enforcing clear social distancing rules and protocols; and
- ▶ Using encounter logs, contact tracing apps or other methods to track the physical whereabouts of occupants and ensure they are complying with social distancing protocols while at the site.

6. MEDICAL SCREENING

Until the current public health emergency ends, all persons seeking entrance to Labs sites must undergo medical screening at checkpoints established at building entrances in accordance with the Medical Screening Policy created by Labs to ensure that medical screening protocols:

- ▶ Respect the privacy rights of persons undergoing screening;
- ▶ Are carried out fairly and consistently without regard to race, age, disability, religion, sex or any other personal characteristic protected by federal and state discrimination laws;
- ▶ Are performed safely by medical professionals or personnel with appropriate medical training using the appropriate PPE and protective equipment; and
- ▶ Comply with the most current Guidelines.

7. SELF-ISOLATION

7.1 Policy Statement

Workers who test positive for, exhibit symptoms of or are at otherwise at high risk of infection due to travel or direct and recent contact with a person that has COVID-19 not be allowed to enter or remain in the workplace and must go into and remain in self-isolation in accordance with current Guidelines.

7.2 Self-Isolation Procedures

Workers that meet the criteria for self-isolation described above must immediately notify their supervisors, explain their situation, e.g., tested positive or symptomatic, and identify all co-workers and others with whom they had close contact at the facility in the past 48 hours. The supervisor will immediately contact individuals identified as having had close contact with the worker and require them to go into self-isolation (subject to exceptions for health care and essential service workers). If workers are at the work site at the time their illness, symptoms or exposure are disclosed, arrangements will be made to safely transport them to their homes or other location where they can self-isolate.

7.3 Return to Work

Workers in self-isolation should remain in regular contact with their supervisors and provide notification of their expected return date as soon as possible. Workers returning to work will be subject to medical screening to verify that they can safely come back.

8. SANITATION & INFECTION CONTROL

Labs will implement appropriate sanitary, cleaning and disinfection measures to minimize the risk of COVID-19 infection, including, at a minimum:

Frequent and regular cleaning and disinfection of surfaces, equipment, door knobs, sinks, handles, keyboards, light switches and other touch points with products approved by the EPA;

- ▶ Keeping wash rooms accessible, clean and amply supplied with soap, water and paper towels;
- ▶ Requiring workers and other occupants to wash their hands frequently while they are present at and immediately before leaving the lab;
- ▶ Posting signs demonstrating proper hand washing techniques in wash areas;
- ▶ Implementing safe work procedures to minimize and ensure the safe handling of mail, packages, materials and goods entering and exiting the lab;
- ▶ Providing all workers clear COVID-19 infection control information and instruction;
- ▶ Requiring all workers to use “respiratory etiquette” and properly cover their mouth when they cough and sneeze;
- ▶ Disciplining workers who don’t follow proper cleanliness and hygiene requirements; and
- ▶ Furnishing and ensuring the proper use of PPE in accordance with Section 9 below.

In addition to the above, Labs will consider and adopt other sanitation and hygiene measures to control COVID-19 infection risks that it deems reasonably practicable, which may include:

- ▶ Installation or refitting of ventilation, air circulating and HVAC systems or equipment;
- ▶ Providing sanitizer dispensers at lab entrances and common areas;
- ▶ Ensuring ample supplies of hand sanitizing wipes to workers for use at their own work stations;
- ▶ Removing doors from hinges;
- ▶ Banning workers from sharing tools or equipment;
- ▶ Removing or restricting use of shared equipment like drinking fountains, coffee machines, kettles, microwaves, fridges, vending machines, water coolers, photocopiers, fax machines and printers; and
- ▶ Establishing “cough safe areas” in locations where people can cough or sneeze without exposing others to infection risks.

9. PPE

When COVID-19 hazards cannot be eliminated or controlled by engineering and/or administrative measures alone, all persons will be required to use appropriate PPE depending on the exposure level assigned to their job classification in accordance with Section 3.1 above.

Continued on page 10

■ Model COVID-19 exposure control plan, from page 9

Job Classification	Required PPE
Very High + High (mostly health care workers, EMTs, ambulance and medical support staff)	N95 particulate filtering masks + protective gloves + aprons at a minimum (more extensive protection such as face shields, goggles, SCBA respirators may also be required)
Medium + Low (vast majority of workers)	Non-medical face masks + protective gloves

Labs will furnish all required PPE to workers at no cost to them and ensure that the PPE:

- ▶ Is properly used, stored and maintained in accordance with the manufacturer's instructions;
- ▶ Properly fits the worker, including by fit testing workers required to use tight-fitting masks that rely on an effective seal;
- ▶ Is safely discarded if it's disposable or is properly cleaned and disinfected if it's designed for reuse; and
- ▶ Is not shared with any other person.

10. SAFETY INFORMATION & TRAINING

All workers at risk of exposure will receive COVID-19 safety information and training covering, at a minimum:

- ▶ How the virus spreads;
- ▶ The fact that there is currently no vaccine for COVID-19;
- ▶ How to reduce the risk of infection;
- ▶ The measures taken by Labs to minimize infection risks; and
- ▶ What to do and who to call if they believe they have been exposed.

11. POSTING

Labs will post a copy of this Plan on its website and in the workplace in one or more conspicuous locations where all workers will be able to see it. 

Get this tool and many others at www.G2Intelligence.com

Quiz: Can Lab Lease Space for COVID-19 Testing to Referring Physician at Below-Market Rent?

SITUATION

ABC Laboratories wants to help a local physician establish a desperately needed COVID-19 testing lab in the community. ABC is willing to lease her the necessary space and testing equipment; it will also let her perform other kinds of testing using the space and equipment. But the physician is strapped for capital and can't afford to pay fair market value rent. ABC understands her predicament and would like to cut her a break on the rent. The problem is that she's a major source of Medicare referrals.

and ABC doesn't want to get into trouble under the Stark Law and Anti-Kickback Statute (which we'll refer to collectively as the "kickback" laws).

QUESTION

Can ABC lease the space and equipment to the physician at below market rent?

- A. No, because charging below market rent is remuneration banned by the kickback laws
- B. No, because the space and equipment will not be used solely for COVID-19 testing
- C. Yes, as long as the arrangement is for the purpose of COVID-19 testing
- D. Yes, because the normal kickback limitations don't apply during the pandemic

ANSWER

C. ABC can lease the space and equipment at below market rent because it will be used for COVID-19 testing

EXPLANATION

In response to the Public Health Emergency (PHE), CMS has issued and the OIG has recognized what are called Blanket Waivers permitting labs and referring physicians to enter into business deals that would normally raise red flags under the kickback laws to the extent the purpose of the arrangement is to provide for COVID-19 testing and treatment. In other words, COVID-19 testing rather than strict compliance is the top priority at the moment.

Among other things, the Blanket Waivers allow labs and other entities to lease space and equipment to referring physicians (or members of their immediate family) at below fair market value rents. As long as the parties act in good faith and with the purpose of providing COVID-19 testing, the arrangement is okay. And that's the case with this scenario. So, C is the right answer.

WHY WRONG ANSWERS ARE WRONG

A is wrong because while leasing to referral sources is a major no-no during times of normalcy, the normal rules can be set aside during a PHE. And that's exactly what happened when CMS issued the Blanket Waivers.

B is wrong because the Blanket Waiver applies as long as providing COVID-19 testing is one of the purposes of the arrangement; it doesn't have to be the sole purpose.

D is wrong because it's an overly broad statement. The Blanket Waivers apply only to COVID-19 testing, subject to the conditions described in the Waiver and CMS guidance. Meanwhile, the normal kickback rules continue to apply for all other kinds of testing during the PHE. 

Labs IN COURT

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

Whistleblower Lawsuit Can't Start Until Criminal Investigation Ends

Case: Two former MedComp Laboratory Sciences employees filed a whistleblower lawsuit accusing the lab of concocting an elaborate scheme to pay kickbacks to a group of 61 physicians in exchange for sending Medicare patient urine samples to a sham reference lab for testing. As it happened, MedComp's alleged scheme was also the subject of a federal criminal investigation. So, MedComp asked the Louisiana federal court to "stay," i.e., delay the whistleblower case until the criminal matter resolved. And that's just what the court did.

Significance: Courts can but don't have to stay civil proceedings when the defendant faces criminal charges involving the same conduct. The court cited the following factors in deciding to exercise that discretion in this case:

- ▶ The whistleblower suit and criminal investigation involved the same issues;
- ▶ Even though nobody had been indicted, the investigation was still active; and
- ▶ Sure, the whistleblowers wanted a quick resolution, but letting the case proceed could force the defendants to invoke their fifth amendment rights against self-incrimination, which would serve only to delay the case.

[*United States ex rel. Bruno v. Schaeffer*, 2020 U.S. Dist. LEXIS 72603]

Feds Arrest Ring Leaders of Alleged COVID-19 False Testing Scheme

Case: Starting in October 2018, a small clique in Georgia made a pretty nice living by gaming Medicare for cancer genetic (CGX) testing. After persuading patients to complete genetic test kits and supply their doctor's name, they'd get doctors' orders for CGX testing by paying kickbacks to co-conspirators at telemedicine companies. In February 2020, the group pivoted to cash in on a new and exciting opportunity: COVID-19 testing. **The deal:** Payment of per-test kickbacks on COVID-19 tests; to jack up profits, they also insisted that COVID-19 tests be bundled with Respiratory Pathogen Panel (RPP) commanding a four-times higher reimbursement rate.

Significance: This may be one of the first enforcement actions targeting a fraudulent COVID-19 billing scam but it will certainly not be the last. That's because COVID-19 fraud has become big business. On March 23, the OIG sounded the alarm on the consumer side by warning patients warning consumers of scammers seeking to exploit "unsuspecting patients" by offering bogus COVID-19 tests and treatments in exchange for personal information such as Medicare numbers (See [LCA, March 30, 2020](#)). Of course, it was only a matter of time before the feds focused on the billing arrangements downstream.

Lab Fires Microbiology Department Manager for Poor Performance, Not Age

Case: A 65-year-old manager claimed LabCorp fired her because of her age; LabCorp contended that she was terminated for poor performance and cited detailed metrics documenting the continued failure of the microbiology department she ran to meet LabCorp performance metrics. But the federal district court didn't buy it and tossed the manager's Age Discrimination in Employment Act lawsuit for lack of hard evidence that age in any way factored into the termination decision.

Significance: Circumstantial evidence may be enough for a plaintiff claiming age discrimination to survive a motion to dismiss and win the opportunity to go to trial. And the manager in this case had one piece of circumstantial evidence that, at least on first blush, looked pretty powerful: the fact that two younger managers didn't get terminated even though the departments they ran also missed their performance metrics targets. But upon closer examination, the smoking gun proved far less. The first younger manager was stripped of her responsibilities for running the department and the only reason she didn't lose her job was that she had a previous assignment with a different LabCorp lab that she could resume after being demoted. As for the second manager with the inadequate productivity metrics, he understood that the handwriting was on the wall and resigned by email in the middle of the night before the ax could fall [*Henderson v. Lab. Corp. of Am. Holdings*, 2020 U.S. Dist. LEXIS 84732].

Pain Clinic, Owner Settle Kickback and False Claims Charges for \$1.35 Million

Case: A Wisconsin pain management and its owner agreed to shell out \$1.35 million to settle charges of accepting kickbacks from a urine drug testing lab in exchange for ordering medically unnecessary tests for Medicare and Medicaid patients under an illegal arrangement that lasted five years and generated thousands of referrals.

Significance: Making the settlement that much harsher is its staying power. Both defendants had entered into an Integrity Agreement with the OIG and agree to make contingent future payments over the next five years based on specific financial criteria. 

Get More of Everything Online
www.G2Intelligence.com

Whistleblowers: Lab to Pay Up to \$43 Million After Disregarding Employee's False Billing Concerns

One of the costliest False Claims Act settlements in recent years is still one more cautionary tale of how dismissing the reports of lab employees who come forward to express internal compliance concerns can fester into a devastating whistleblower lawsuit.

The Whistle Blows

The concerned-employee-turned-whistleblower in this case was the board-certified physician hired by North Carolina-based Genova Diagnostics as Chief Medical Order tasked with responsibility to develop medical necessity evidence for IgG allergen, NutrEval and GI Effects, three of the firm's unconventional test profiles. Over time, he realized that there was no such evidence and advised the lab not to bill Medicare, TRICARE and private insurers for the tests.

The Lab Plugs Its Ears

He claims that Genova dismissed his concerns as “overly conservative,” and then cut his department's budget, before excluding him from management meetings and eventually firing him over what he contended were trumped up employment misconduct charges. So, the whistleblower took his case to federal court [*United States ex rel. Darryl Landis, M.D. v. Genova Diagnostics, Inc., et al.*, No. 1:17-cv-341 (W.D.N.C.)].

The Feds Get Involved

The DOJ entered the scene, charging Genova with falsely billing for IgG allergen, NutrEval and GI Effects tests, citing the lack of published, peer-reviewed or high-quality clinical studies demonstrating the effectiveness of the tests. And since the tests weren't scientifically proven effective at diagnosing any medical conditions, they weren't deemed medically necessary under Medicare coverage rules. The DOJ also accused Genova of falsely coding the tests and paying compensation to phlebotomy vendors in violation of the Stark Law.

The Price of Settlement

After doing its own internal assessment, Genova concluded that it had done nothing wrong. But facing the risk of litigation and prosecution, it decided that discretion was the better part of valor and settled the case. The price tag could run as high as \$43 million, including:

- ▶ Over \$17 million in Medicare and TRICARE payments forfeited; and
- ▶ Additional penalties of 13% of any net annual revenue above \$100 million and 20% of any asset sales over \$1 million over the next five years, subject to a \$26 million cap.

The whistleblower stands to collect up to \$6.5 million of this award. 

Medicare Reimbursement: CMS Waivers Expand COVID-19 Testing Coverage Rules

On May 1, CMS issued [regulatory waivers](#) temporarily expanding coverage and clarifying billing of COVID-19 testing for Medicare and Medicaid beneficiaries during the public health emergency (PHE). Here are the five key takeaways.

1. CPT Coding

Labs can be paid for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code CPT 99211. During the PHE, CMS will recognize this code for billing all patients, not just established patients.

2. No Need for Written Order

CMS will also waive the requirement of a written practitioner's order for purposes of Medicare reimbursement of COVID-19 tests, including tests to confirm or rule out COVID-19. CMS still expects to furnish test results to beneficiaries, typically within 24 hours.

3. Expansion of Eligible Test Orderers

CMS will no longer require an order from a treating physician or other practitioner for a beneficiary to get tested for COVID-19 but will cover testing ordered by any healthcare professional authorized to order tests under state law. The waiver also applies to other tests required as part of coronavirus testing.

4. Green Light for Evaluation & Sample Collection by Pharmacists

Another CMS waiver allows pharmacists to work with practitioners to evaluate beneficiaries and collect samples for testing. Practitioners may bill Medicare for these services. To clear the way for drive-through testing, pharmacists enrolled in Medicare may perform certain COVID-19, in accordance with state law and licensing requirements.

5. Coverage of Serology Tests

Last but not least, CMS said that Medicare and Medicaid will pay for coronavirus serology tests. The two programs will cover lab processing of certain FDA-authorized tests that beneficiaries self-collect at home. 

We're Mobile Friendly at www.G2Intelligence.com

■ Brief Your CEO: The 18 Things You Can Do for COVID-19 that You Can't Do for Other Testing, from page 1

agency exercised that discretion by issuing [Blanket Waivers](#), aka Section 1135 waivers, clearing the way for COVID-19 testing arrangements that would otherwise raise red flags under the Stark Law for as long as the PHE remains in effect.

But it soon became evident that the Stark waivers weren't enough. The problem was that many of the COVID-19 testing arrangements that labs and physicians wanted to make implicated not only Stark but also the federal Anti-Kickback Statute (AKS) which bans offering, requesting or payment of "remuneration" to referral sources to induce or reward referrals. So, on April 3, the OIG issued a Policy Statement to indicate that it was all behind the Stark Law Blanket Waivers and would exercise its discretion not to seek AKS penalties against providers that entered into COVID-19 testing business relationships permitted by the Waivers.

The 18 Blanket Waivers

The heart of the briefing is a description of which COVID-19 testing arrangements are now on the table. But first you need to provide your CEO an important caveat. Explain that the OIG's AKS non-enforcement policy doesn't go as far as the CMS Blanket Waivers under the Stark Law. Specifically, the OIG covers only the first 11 of the 18 arrangements listed in the Blanket Waivers. Having clearly pointed this out, go through the list of Blanket Waivers.

1. **Compensation for Physician Services:** A lab or other entity (which for simplicity's sake, we'll refer to collectively as "lab") may provide remuneration that's above or below the fair market value to physicians for services they personally perform for the lab.
2. **Office Space Rentals:** During the PHE, labs can pay physicians (or their immediate family members) rental charges below fair market value for lease of office space from the physician.
3. **Equipment Lease Rental Charges:** Labs can also lease equipment from the physician at below fair market rent.
4. **Purchases of Goods & Services:** You can also make below fair market value purchases of items or services from a physician, e.g., purchase of an unused respirator from a physician.
5. **Below Market Rent:** The flipside of Blanket Waiver 2 is that a physician can lease office space from a lab at below fair market value rent.
6. **Below Market Equipment Equipment Rental:** Similarly, Waiver 3 can also work in reverse with physicians leasing equipment from the lab at below market rent.

7. **Below Market Use of Premises:** Physicians can provide a lab below fair market value remuneration for use of the lab's premises, e.g., for use as a COVID-19 satellite office, or to purchase items or services from the lab.
8. **Medical Staff Incidental Payments in Excess of Limits:** Remuneration from a hospital to a physician can be in the form of medical staff incidental benefits above the normal limits set out in the Stark Law regulations, currently \$423 per year.
9. **Non-monetary Compensation Above Limits:** Remuneration from a lab to a physician can be in the form of nonmonetary compensation that exceeds the normal limits set out in the regulations.
10. **Below Market Loans to Physicians:** Labs can offer referring physicians loans at below market interest or on favorable terms unavailable absent referrals.
11. **Below Market Loans from Physician:** Conversely, referring physicians can offer labs loans at below market interest or on favorable terms unavailable absent referrals.

Intermission: The Blanket Waiver Blind Spot Reminder

Pause at this point to remind your CEO that the OIG AKS non-enforcement policy applies only to the previous 11 items. Bottom Line: While permissible for purposes of the Stark Law, entering into the remaining COVID-19 testing arrangements is still subject to enforcement action and prosecution under the AKS and will thus have to be structured to take advantage of applicable AKS exceptions and safe harbors.

12. **Temporary Expansion of Physician Owned Hospital Beds:** The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed is allowed, provided that it serves a COVID-19-related purpose.
13. **ASC to Hospital Conversions:** Referrals by a physician owner of a hospital that converted from a physician owned ambulatory surgical center to a hospital on or after March 1, 2020 are also allowed for COVID-19 purposes, but subject to specific limitations.
14. **Home Health Referrals:** Similarly allowed are referrals to a home health agency that doesn't qualify as a rural provider and in which the referring physician has an ownership or investment interest.
15. **DHS Not in Same or Centralized Building:** To DHS services available at remote or temporary treatment locations, the CMS is allowing referrals by a physician to a group practice designated health services location that does not qualify as a "same building" or "centralized building."

Continued on page 12

■ Labs In Court, From Page 17

16. **Referrals for DHS in Patient's Home:** This Waiver permits referral by a physician in a group practice for medically necessary designated health services furnished by the group practice to a patient in his/her private home, an assisted living facility or independent living facility where the referring physician's principal medical practice doesn't consist of treating patients in their private homes.
17. **Rural Referrals:** The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area is now permitted for COVID-19 purposes.
18. **Waiver of Written Signature:** CMS has temporarily waived the requirements that a compensation arrangement satisfy writing or signature requirement(s) as long as the arrangement satisfies each other requirement of the applicable exception, unless such requirement is waived under one or more of the blanket waivers set forth above.

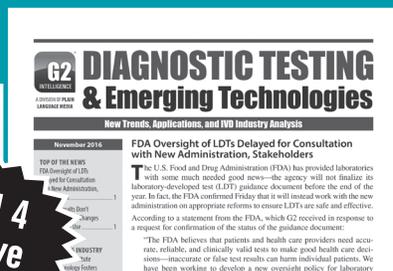
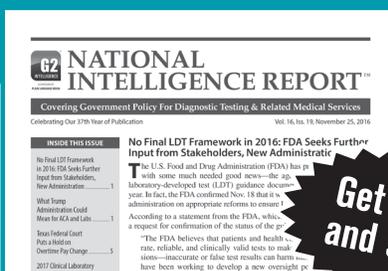
Takeaway

The one thing you want your CEO to take away from this briefing is that the foregoing Blanket Waivers are temporary and apply only if the arrangement is necessitated by the pandemic, such as awarding physicians "hazard pay," giving away lab space or equipment to create new COVID-19 testing clinics or paying a key physician's transport and travel expenses to ensure his/her availability for COVID-19 purposes. For all other forms of lab testing and treatment, the normal Stark Law and AKS restrictions still apply.



Special Offer for Lab Compliance Advisor Readers

Test Drive all 4 G2 Intelligence Memberships and SAVE!



Get all 4 and save

Contact Andrea at 888-729-2315 or Andrea@PlainLanguageMedia.com for details on this special offer.