NELSON HARDIMAN
HEALTHCARE LAWYERS

Client Alert: Priority Guidelines FAQs: Establishing Worksite Covid Testing

According to Gallup, roughly 75% of the American workforce have been vaccinated. According to one assessment by former FDA commissioner Dr. Scott Gottlieb, close to 90% of US residents have some form of immunity to Covid-19, acquired either through vaccination or infection. When combined with the abundance of OTC rapid-tests now available (and accessible) in the marketplace, many employers have taken steps to return to the office, curtailing remote work, and encouraging employees to return to the worksite. Since many OSHA regulations and State law requires employers to maintain a safe work environment, we have been receiving many questions from employers wanting guidance when it comes to establishing workplace testing and testing policy. Below are some of our most Frequently Asked Questions:

1. How do we get started with implementing testing protocols?
First, decide if testing will apply to all, or if vaccinated individuals will receive testing exemptions, akin to mask exemptions for those that are fully vaccinated (depending on local mandates). If vaccination status is going to make a difference to your worksite testing policy, then the next step is to take a census. In most states, including California, it is lawful for an employer to inquire as to the vaccination status of an employee. However, several states, including Alabama, Florida, Iowa, Montana, and Texas, prohibit businesses from inquiring into the vaccination status of employees.

2. How should employee Covid-19 records, regarding vaccinations or infections, be stored? First, all employee personal status information should remain confidential, including vaccination status, test results, or information regarding an infection. (One can tell other employees they have been exposed to Covid-19 without disclosing the source of the exposure.) Essentially, Covid-19 employee information should be treated like any other medical information. As such, it must be kept separately from regular personnel information. These records must be stored securely, whether they are kept digitally or in hard copy. It is always possible that local health agencies may need your business's Covid-19 data to do contact tracing or as part of their research on contagion spread. But otherwise, (for non-healthcare entities) this information does not require submission to any agency at this time. The one exception is if there is a work-related Covid-19 fatality. In the event of such a misfortune, the link for California businesses is found here: CAL/OSHA; while the link for national reporting requirements is available here.

3. Does my business need laboratory CLIA Certification for OTC rapid tests? In general, if the tests are self-administered, CLIA certification is not required. This includes the following scenarios:
a. If employees perform and interpret their own Covid testing using an OTC test intended for home use and provide/show the result to the employer.
b. Similarly, if an employer or another entity provides OTC test kits to employees so they can test and interpret the results themselves.
c. If an employee of the company merely collects and labels test samples provided by employees. The samples are then sent for Covid testing in CLIA certified authority.
d. Lastly, if an outside CLIA certified facility is contracted to perform Covid-19 testing on the employees.

4. Under what circumstances is CLIA certification necessary?
a. When a business decides to use a FDA test kit authorized for clinical use, rather than a "point-of-care" OTC kit intended for home use.
b. When a business has an employee of their organization (whether its other staff or health personnel) performing the testing on its employees. It is irrelevant if it is an OTC test or a "clinical use" kit.
c. In any situation where someone other than the employee is interpreting the test result.

5. How can I get CLIA certification for my business? CMS provides a useful guide to obtaining a CLIA certificate of Waiver. There is a $180 fee. Check with your local jurisdiction, as some states may have additional requirements.

6. Can a group health plan cover testing costs? Depending on the number of employees and frequency of testing, testing can be costly. One should inquire with the business's group health plan, if applicable, for potential coverage. If a provider determines that a test is medically necessary for an individual (such as when there has

been exposure), then under the under the CARES Act and Families Coronavirus-19 First Act, group health plans must cover the cost of testing. In general, surveillance testing is likely not covered by some group health plans. In California, a recent bill (SB-510) requires healthcare plans to bear the cost of "screening testing," which includes all of the following:
a. Workers in a workplace setting.
b. Students, faculty, and staff in a school setting.
c. A person before or after travel. […]

7. Must employees be compensated for time devoted to testing? According to the Department of Labor, when testing is required by an employer, the time an employee devotes to getting tested is considered work hours for compensation purposes. (FLSA FAQs #7) Under the current California mandate, there are similar requirements to pay employees for time devoted to testing and to cover the cost of testing. (We discuss the latter in previous post.)

8. How do I start creating a written Covid-19 policy now that my employees are returning to the office? CAL/OSHA created a useful template which can be adapted and adopted.

9. How often should employees be tested? When there are outbreaks, exposures, incidents of illness, or out-of-state travel, testing effected/exposed individuals is mandatory under local California ordinance. But for regular safety surveillance, the answer is it depends. Every business has its own unique dynamics which should be carefully considered before choosing the most suitable testing strategy, i.e. weekly, bi-weekly, or daily checks…

Nelson Hardiman LLP
Healthcare Law for Tomorrow

Nelson Hardiman regularly advises clients on workplace policies related to Covid-19. We offer legal services to businesses at every point in the commercial stream of medicine, healthcare, and the life sciences. For more information, please contact us.

Authored By:

Yehuda Hausman, Law Clerk

Harry Nelson, Managing Partner

VIEW CLIENT ALERT

This article is provided for educational purposes only and is not offered as, and should not be relied on as, legal advice. Any individual or entity reading this information should consult an attorney for their particular situation.