LOCKTON

UNCOMMONLY INDEPENDENT

COVID-19 questions and answers for U.S. employers:

Health coverage

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Please note: *The spread of the coronavirus (COVID-19) is a quickly changing situation. For the most up-to-date information and resources, visit the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (NIOSH). The CDC should be your primary source for emergency preparedness and response to the coronavirus. The below information is designed to guide businesses to known, credible online resources covering the coronavirus and does not constitute medical advice.*

Employers with offices outside the U.S. should review their statutory obligations for reporting suspected cases and paid time off policies with employment counsel to ensure compliance with local and national legislation.

Sections:

Health coverage

Medical plan/HSA

Should we consider excluding coronavirus testing as a covered service?

Instituting any sort of blanket exclusion within your plan for coronavirus testing and treatment is not recommended, not only because of risk of claims under the Americans with Disabilities Act and HIPAA, but as a matter of public policy and employee relations. It may also be difficult, in at least some cases, to pinpoint exactly what treatments or

therapies to exclude, an issue that could be aggravated by the potential for inadequate or vague provider coding of claims.

Is our health plan *required* to cover the cost of coronavirus testing? Can we apply the deductible or other cost-sharing requirements, like copayments?

The new Families First Act requires all medical plans to cover, with no member cost sharing, coronavirus testing *and the related doctor's visit (presumably whether in person or via telemed),* without imposing cost sharing (e.g., deductibles, copays or coinsurance). Nor may the plan impose any preauthorization or medical management requirements for coronavirus testing. The new coverage requirement does not require plans to waive cost sharing for coronavirus *treatment*.

Pharmacy

I have heard that the coronavirus might lead to drug shortages in the U.S.? Why is that? What is the connection between what's going on in China and what is on the shelves of my local pharmacy here in the U.S.?

Medications are composed of a complex combination of inactive and active ingredients. In a typical tablet, for instance, the majority is made of inactive or inert ingredients, designed to hold the dosage form together and to make the administration of very small amounts of active ingredient easy and consistent. Active pharmaceutical ingredient (API) is the "active drug" component of a tablet or capsule. In a typical 10 mg tablet or capsule of any drug, the majority of its mass is composed of inactive or inert ingredients, while only a very small percentage is composed of API.

Today, the greatest concentrations of API manufacturers to meet worldwide demand are located primarily in China and India (approximately 80%). Of note, the use of China as a primary source for worldwide API supply impacts both brand and generic pharmaceutical manufacturers, as companies increasingly rely on outsourced API.

As China has taken steps to control the spread of the coronavirus within its borders, all its manufacturing processes have been curtailed as workers are ordered to stay at home to limit the opportunities for the disease to spread through direct person-to-person contact. This is why, depending upon the length of time the API manufacturing slow-down persists in China, drug supply in the U.S. may be negatively impacted.

In a statement issued on Feb. 27, 2020, the FDA indicated:

"A manufacturer has alerted us to a shortage of a human drug that was recently added to the drug shortages list. The manufacturer just notified us that this shortage is related to a site affected by the coronavirus. The shortage is due to an issue with manufacturing of an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients. We are working with the manufacturer as well as other manufacturers to mitigate the shortage. We will do everything possible to mitigate the shortage.

Since January 24, the FDA has been in touch with more than 180 manufacturers of human drugs, not only to remind them of applicable legal requirements for notifying the FDA of any anticipated supply disruptions, but also asking them to evaluate their entire supply chain, including active pharmaceutical ingredients (the main ingredient in the drug and part that produces the intended effects, e.g., acetaminophen) and other components manufactured in China.

Also, as part of our efforts, the FDA has identified about 20 other drugs, which solely source their active pharmaceutical ingredients or finished drug products from China. We have been in contact with those firms to assess whether they face any drug shortage risks due to the outbreak. None of these firms have reported any shortage to date. Also, these drugs are considered non-critical drugs.

We will remain in contact with manufacturers so that we can continue to assist them with any potential issues in the fastest way."

When pressed further to identify the specific drug in question, the FDA indicated that the name of the drug in question is confidential commercial information. They explained:

"While manufacturers are legally required to report drug supply disruptions to FDA, they are not required to provide the detailed information on their supply chain that we have needed to monitor the drug supply since the onset of the outbreak … We need the cooperation of the drug companies in order to obtain accurate information as we proactively take steps to mitigate drug shortages, and companies will be less willing to provide this voluntary information if they cannot trust FDA not to discloses commercial confidential information such as drug names, company names or exact location of facilities."

For these reasons, Lockton is unable to determine the specific names of any drugs potentially looming to be in short supply, but the fact that 80% of the world's API is currently manufactured in China and India remains the broader fact to keep in focus as time goes by.

Are reports that ibuprofen should not be used in someone who has tested positive for COVID-19 accurate?

On March 19, 2020, the FDA issued a statement that it is not aware of scientific evidence connecting the use of non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen with worsening COVID-19 symptoms. The FDA stated that it is investigating this issue further and will communicate publicly when more information is available. The FDA also noted that all prescription NSAID labels warn that by reducing inflammation, and possibly fever, these drugs may diminish the utility of diagnostic signs in detecting infections.

Has hydroxychloroquine has been approved by the FDA to treat COVID-19?

No, the FDA has not approved hydroxychloroquine for use in the treatment of COVID-19. Currently the FDA has a clinical trial to assess the safety, efficacy and dosing of hydroxychloroquine in the treatment of COVID-19, and these results will determine under what circumstances it might be approved. Hydroxychloroquine is approved to treat malaria and certain auto-immune disorders, such as rheumatoid arthritis and lupus. Without the FDA's approval, its use in the treatment of COVID-19 would be considered "off label," which might make physicians unwilling to prescribe it for this new use, make payer organizations unwilling to pay for it, and render it ineligible for coverage under health plans' SPDs if they exclude drug coverage for off-label or "experimental" uses. Please click to read the official FDA notice.

FFCRA

The Families First Act (FFA) imposes a requirement on all government employers, and private employers with fewer than 500 employees, to offer two weeks of paid sick leave, and 12 weeks (including 10 weeks of paid leave) of expanded Family and Medical Leave Act protection. How do I determine if my company must comply with FFA requirements because it has fewer than 500 employees?

Before we get to *how* we count employees, let's consider *who* we count. An employer should include in its count all full-time employees, part-time or variable employees, employees on leave, temporary employees who are jointly employed by, for example, a worksite employer and another employer, like a staffing firm, and day laborers supplied by a temporary agency. No exemption is offered for an employer's direct hire

temporary or seasonal workers. However, non-US employees and true independent contractors are not included in the count.

The Department of Labor (DOL) says the count should occur as of the first day of an employee's leave, which may make this a bit of an administrative nightmare absent exceptional employee tracking.

To determine whether the employer has fewer than 500 employees, the employee count is generally made on an EIN-by-EIN basis, with all employees in the entity's various divisions included in the count. In addition, if the entity employs anyone deemed to be a joint employee (the usual suspects are employees of temporary staffing agencies, for example) individuals must be added to the entity's overall employee count.

Joint employment might exist, for example, where one employer (e.g., a staffing agency) hires, set the hours, pays and has the right to fire an employee, but another employer (e.g., the worksite employer, that staffing agency's client) supervises and controls the employee. The DOL has issued regulations outlining when a joint employment relationship exists. Those regulations will be helpful in completing the joint employment analysis.

The final step in the analysis looks to see if, where entities are commonly owned in whole or in part, the separate entities must be considered together. This aggregation could push the overall employee count to 500 or more. If that were the case, *all* aggregated entities would be exempt from both the new paid sick leave requirement and the expanded FMLA requirement.

Separate entities must aggregate employee counts if the entities are considered "integrated." Unfortunately, the test for integration is subjective, making it difficult to be certain when two or more entities must be aggregated. That's a problem because, for example, two entities that should *not* be aggregated might treat themselves as integrated and, as a result, one or both will fail to comply with the new paid sick leave and expanded FMLA requirements. If they *should* be aggregated but they're not, and they comply with the new sick leave and expanded FMLA rules *and claim tax credits for having done so*, they will have claimed those credits inappropriately.

So, what's the test for integration? From a benefits perspective, we are familiar with the Tax Code's "controlled group" rules that consider, generally speaking, the percentage of stock or profits interest in one entity owned by another, and requires at least 80% common ownership to aggregate the separate entities and treat them as a single employer for benefits nondiscrimination testing, for example. In contrast, the integration

test – while requiring at least *some* common ownership – treats as relatively unimportant the *actual percentage* of that ownership.

Common ownership is just one of four factors (and as noted, is the least important factor) under the integration test to determine if entities must be aggregated. Three other factors must also be considered. They are:

- *Centralized control over labor relations.* This is the most important factor. Common human resources function, use of the same employee handbook, use of the same HR policies, and/or one entity making decisions for both regarding employment matters or wage setting – all of these facts lean in favor of integration.
- *Interrelation between operations.* A shared location/headquarters, common benefits plans, centrally set operating budgets for all, and common recordkeeping all tilt toward integration.
- *Common management.* A significant overlap in management and human resources make a strong case for integration.

Thinking about the integration test

In some cases, this analysis won't be necessary. If all entities, when aggregated, won't reach the 500-employee count, or when each separate entity easily surpasses the 500-employee count, there's no point in conducting an integration analysis.

In most cases, we suspect entities in a private equity portfolio will not be considered integrated employers. Nor will franchise operators be integrated with the franchisor.

But in other cases, where the determination matters, employers will want to consult their labor and employment law attorneys for advice on whether they should be considered integrated with other employers.