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Opening the Doors: Return-to-Workplace Considerations During COVID-19

U.S. Regulatory

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Food, Drug, and Device

Businesses are developing plans for reopening workplaces. As they do, many employers are considering ways to determine which employees can safely return to the workplace, and what protective equipment should be provided to employees once they return. In both the United States and European Union, many of the products used in these strategies are regulated as medical devices. This alert provides an overview of key U.S. regulatory issues companies should consider as part of their return-to-workplace (RTW) strategies. In a separate alert, we will provide an overview of similar issues in the EU and UK.

The alert is part of Covington's "Opening the Doors" series, which addresses RTW considerations for employers. Previously, we released a five-part series addressing the employment issues associated with RTW: Opening the Doors: Return-to-Workplace Considerations During COVID-19. More broadly, Covington has established a COVID-19 Task Force and Toolkit for our clients, addressing the numerous legal issues associated with the COVID-19 pandemic.

Feel free to reach out to any of the Covington contacts listed at the end of this alert, or email our COVID-19 Task Force at COVID-19@cov.com with questions.

Testing at the Door: Determining Who Can Enter the Workplace

Employers implementing return-to-workplace programs potentially will employ a variety of screening mechanisms—thermometers, digital health tools, and diagnostic tests—in an effort to determine who is safe to enter the workplace, all of which can trigger important regulatory considerations.

FDA Regulation of Thermometers and Temperature Scanning Products

For temperature screening of employees, employers may consider using two types of products: (1) electric thermometers, including non-contact thermometers; and (2) "telethermographic systems" that detect infrared radiation and convert the information into a body temperature measurement. In the U.S., such products typically require FDA review and clearance prior to marketing and are subject to a variety of regulatory controls for medical devices. However, during the public health emergency, FDA has issued enforcement polices for thermometers and telethermographic systems waiving the requirement that these products receive FDA clearance as well as certain other device regulatory requirements.

FDA generally does not regulate the *use* of medical devices by healthcare professionals, patients or other lay persons. Companies utilizing thermometers or other temperature screening devices are not subject to FDA regulation. However, companies should consider whether the device they utilize in employee screening is labeled consistently with the company's use, for example, whether the thermometer or telethermographic system is labeled for prescription use as compared to over-the-counter (OTC) use. Moreover, to ensure appropriate device performance and the safety of employees, companies should closely review the device labeling. In addition, FDA has provided guidance on its website regarding the proper preparation of the screening environment and device set up for telethermographic systems.

FDA Regulation of Digital Health Tools for Assessing COVID-19 Risks or Symptoms

Digital health screening tools may ask employees about risks for exposure to COVID-19 (e.g., COVID-19 status of individuals in the employee's household, COVID-19 testing history, social distancing practices) or about the individual's symptoms (such as those identified by the U.S. Centers for Disease Control and Prevention (CDC)). Some digital health tools may simply transmit that information to a medical professional for assessment, while other tools may provide an assessment of the individual's exposure risk directly to the individual and/or the employer.

Depending on the functionality and intended use of the digital health tool, it may be subject to regulation as a medical device. FDA has not announced a specific enforcement policy for screening, assessment or other clinical decision support tools specific to COVID-19. Under FDA's existing digital health policies, FDA generally does not regulate tools that match user-specific information (e.g., symptoms) to established reference information (e.g., CDC guidelines). Likewise, tools intended to help a patient document their health, that track and trend (but do not analyze) a patient's data, and/or communicate health information with a healthcare professional are not regulated as devices. On the other hand, under FDA's existing software policies, FDA would likely regulate as a medical device a tool that provides patient-specific recommendations on COVID-19 diagnosis, if the tool does more than automate health authority guidelines.

While companies utilizing screening tools developed by third parties will generally not be subject to FDA regulation themselves, firms that develop (or co-develop) their own digital health tools could be subject to regulation as a device manufacturer, depending on the functionalities of the product. Companies developing tools, including those contracting out certain elements of the development, should carefully consider whether FDA or other regulators will actively regulate the tool as a device.

FDA and CMS Regulation of COVID-19 Diagnostic Tests

While temperature screening and digital health tools may suggest which employees should be tested further, many employers are considering a more direct strategy: to use diagnostic tests to determine which employees may be infected. However, diagnostic testing implicates a number of regulatory matters, as both the tests themselves and their use may be subject to regulation.

In the U.S., the regulation of diagnostic testing involves both FDA and the Centers for Medicare & Medicaid Services (CMS). FDA is responsible for reviewing COVID-19 tests before they enter the market and assigning the setting (the type of lab) where such tests may be performed. CMS

regulates testing by laboratories under the Clinical Laboratory Improvement Amendments (CLIA).

To date, FDA has authorized a large number of tests under Emergency Use Authorizations (EUAs). Such tests fall into two general categories:

- **Molecular and Antigen Tests**. These tests detect genetic material or proteins from the SARS-CoV-2 virus from clinical samples to diagnose a patient's current COVID-19 status. Currently, FDA has authorized most molecular/antigen tests to be performed in facilities certified under CLIA to conduct moderate or high-complexity testing. FDA has authorized a small number of these tests to be performed at the point of care by an entity that has a lower level CLIA certificate, called a CLIA "Certificate of Waiver."

- **Serological or Antibody Tests**. A serology test is conducted on a sample derived from the blood to identify antibodies to SARS-CoV-2. These tests generally determine if a person was previously infected with the virus, but may not indicate active infection. For this reason, these tests are not considered to be a sole diagnostic test for COVID-19, and positive results should be confirmed by a molecular/antigen test. Currently all serological tests must be administered by a facility certified to conduct moderate or high-complexity testing. No serological tests are currently authorized by FDA for use as point of care tests.

FDA has not authorized any OTC or home use tests (although tests have been authorized for home collection). Moreover, CMS has not altered its traditional requirements for facilities performing COVID-19 diagnostic testing. Under current CMS policy, employers that perform testing are subject to regulation as a laboratory and must obtain an appropriate CLIA certification.

Therefore, at this time, a company may begin its own COVID-19 diagnostic testing only if it obtains a CLIA certificate and performs tests that align with that type of CLIA certificate. Given the expertise and resources needed to stand-up a laboratory and obtain CLIA certification, this may not be feasible for most employers. Alternatively, companies may consider partnering with a third-party laboratory to conduct testing. Companies pursuing this pathway should confirm that the lab partner uses an FDA-compliant COVID-19 test and maintains appropriate CLIA certification based on the type of test performed.

Both FDA and CMS have indicated that they are exploring ways to permit more widespread testing to facilitate reopening of businesses, which may include authorizing tests for use on asymptomatic patients, relaxing certain CLIA requirements, or issuing guidance on how to implement testing consistent with regulatory requirements. In addition, some states are considering policies to relax otherwise applicable requirements that COVID-19 testing be done pursuant to prescriptions. This area is evolving quickly, and employers should keep abreast of current developments.

Other Regulatory Considerations Raised by Employee Screening Practices

In addition to the above considerations, all of the above screening/testing options raise a host of other regulatory and legal issues. These include (but are not limited to) the following:

- **Privacy Laws**. Companies will need to carefully consider state and federal privacy laws regarding the data generated and collected from employees through temperature screening, digital health, and diagnostic testing programs, including the legal basis for processing sensitive data, what employee consents may be required and what data security controls would need to be implemented.
- **Practice of Medicine and Medical Licensure**. Companies performing temperature screening (if not using over-the-counter devices) or administering diagnostic tests to employees will need to assess whether such practices must be conducted by a licensed professional. Likewise, companies should consider whether discussions related to test results or elevated temperatures implicate medical licensure and practice of medicine requirements. Many state and local jurisdictions also require notification to governmental authorities of positive test results.
- **Employment Law**. Companies will need to consider employment law requirements (including Americans with Disabilities Act restrictions) when determining the scope of information or testing that may be requested (or required) from employees. Parts Two and Five of our Return-to-Workplace Series address employee screening measures.

Protecting Employees in the Workplace

In addition to screening employees returning to the workplace, employers will use a variety of different strategies to ensure the safety of employees in the workspace, including enhanced cleaning protocols, workplace social distancing measures (such as staggered work hours, limitations on in-person meetings, distancing of work stations, etc.), use of masks and other personal protective equipment (PPE), availability of hand sanitizers, training of employees, and procedures for reporting and responding to any positive COVID-19 cases in the workplace.

While many of these approaches do not involve medical devices or implicate FDA considerations, employers should be aware that face masks and other PPE are regulated as medical devices by FDA when intended for medical use. This includes face coverings, masks and respirators used by employees or the general public during the COVID-19 pandemic to reduce the risk of transmission of the virus. FDA does not regulate the use of face masks, but companies should be aware of the regulatory framework, particularly if importing masks or producing masks for employee use, which may trigger FDA requirements.

Regulatory Considerations for Masks and Other PPE

Companies providing face masks to employees to limit the transmission of COVID-19 in the workplace should be aware of the distinctions between the different types of masks, the level of protection they provide, and the level of regulatory review they receive, and should ensure that the masks provided to employees are compliant with applicable requirements. During the public health emergency, FDA has issued an enforcement policy waiving many of the typical medical device requirements for masks and certain PPE that meet certain criteria. The agency has also issued EUAs authorizing the distribution and use of various masks and PPE, if certain conditions are met. In addition, companies who are importing masks from sources outside the U.S. should be aware of the regulatory framework when importing masks and PPE.

These policies create a complex regulatory paradigm for PPE:

Non-surgical Face Masks

FDA has issued an EUA as well as an enforcement discretion policy permitting the distribution/use of face masks by the public and healthcare professionals. Manufacturers may market masks without any review by FDA and are not subject to many of the other traditional medical device requirements, so long as they meet certain conditions described by FDA in the EUA and enforcement discretion policy.

Surgical Masks

Surgical masks intended to provide liquid barrier protection typically require FDA clearance. But under the enforcement policy, FDA has waived this requirement so long as the masks meet certain performance and labeling requirements.

NIOSH-approved Respirators

Typically, FDA does not regulate respirators intended for general/industrial uses, which are regulated by the National Institute for Occupational Safety and Health (NIOSH), including N95 masks. FDA has issued an EUA permitting the distribution and use of NIOSH-approved respirators for use by healthcare professionals in healthcare settings.

Imported Respirator Masks

FDA has issued two EUAs for imported, non-NIOSH-approved respirator masks. One EUA permits the distribution for use by healthcare professionals of imported respirators that meet certain other international standards similar to the N95 standard. The other EUA permits the distribution for use by healthcare professionals of respirators manufactured in China where the respirators meet certain criteria and the manufacturer submits information to FDA. Employers should be aware that FDA recently removed a number of masks manufactured in China from the EUA due to concerns about their performance. In addition, the enforcement policy permits the import of respirators not authorized under these EUAs, if listed in CDC crisis capacity strategy guidelines.

Use of masks and PPE in the workplace raises a number of additional regulatory considerations, such as compliance with OSHA requirements, as well as employment law considerations. These considerations are discussed in Part 3 of Covington's Return-to-Workplace series, General Workplace Safety Precautions.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drug, and Device practice:

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