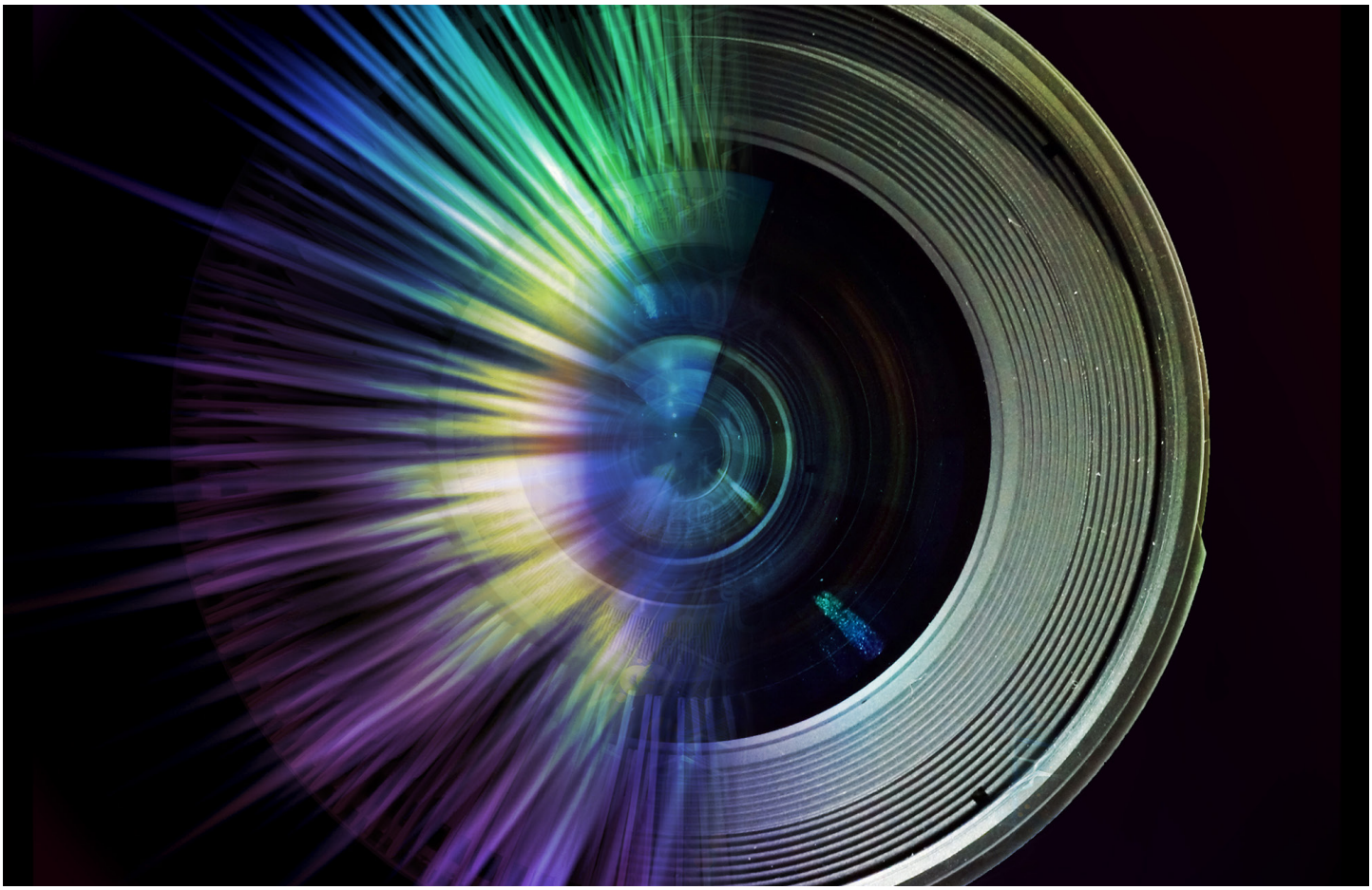
Deloitte.



PPE supplier vetting during the coronavirus pandemic

Balancing urgency and risk

PPE Supplier Vetting During the Coronavirus Pandemic—Balancing Urgency and Risk

As the spread of coronavirus (COVID-19) has accelerated across the US, health care providers, governmental entities, and essential businesses have been working to secure scant supplies of personal protective equipment (PPE) for workers and caregivers. As a result, purchasing agents may face pressure to eschew traditional means of vetting suppliers and potentially expose themselves to doing business with fraudulent or inexperienced suppliers.

Conducting accelerated supplier vetting, even at a high-level, can help provide purchasing agents with answers to pertinent questions about their potential business partners, thereby helping to inform their decision-making process. Following are some of the considerations that may be weighed in this process.

If the supplier is registered with the Food and Drug Administration (FDA), can it be relied upon for vetting?

According to the FDA, PPE refers to equipment—including gloves, clothing, facemasks, and respirators—that is "designed to protect the wearer from injury or the spread of infection or illness."[1] If the end user of PPE is a medical professional, the PPE is considered a medical device and is subject to FDA regulations and "should meet applicable voluntary consensus standards for protection."[2]

Registration with the FDA can provide purchasing agents with key data points on the potential supplier, including its corporate contact person or entity, that can be cross-referenced from other sources.

Registration with the FDA also may signal that the potential supplier has, at some point, been active in the healthcare industry. However, while medical device suppliers are required to be registered with the FDA, the FDA cautions that registration does not, by itself, "denote approval or clearance of a firm or their devices."[3] In addition, the FDA has invoked emergency measures to allow for the provision of certain PPE—including facemasks and ventilators—by unregistered suppliers.[4] Therefore, when deciding whether to conduct business with a prospective supplier, additional vetting measures on the supplier and its distributor(s) are recommended, regardless of FDA registration status.

What additional steps can be taken to identify information on a potential PPE supplier?

In addition to identifying a potential supplier's FDA registration status, purchasing agents may take further steps to understand the entity and/or related individuals that are alleging to provide PPE. Potential steps may include the following:

- If applicable, search FDA databases for reports of adverse events or recalls, or whether the entity has been issued a warning letter
- Confirm corporate registration information and status, and identify the entity's principals
- Review online presence, including the entity's website, for legitimacy
- Analyze international shipping records for import/export transactions
- Perform a review of global regulatory and sanctions searches on the entity and its principals
- Conduct pinpointed searches for adverse or relevant media on the entity and its principals
- Identify litigation involving the entity and its principals
- Determine whether the entity or its principals have filed for bankruptcy

What risks arise from insufficient vetting?

By not conducting a degree of third-party due diligence, purchasing agents may find themselves entering into high-value business transactions with entities and individuals that are unknown and unverified, leading to several potential short-term and long-term consequences:

Fraudulent or fictitious suppliers

The scramble to obtain PPE, particularly N95 respirator face masks, has created a space for fake and counterfeit products and unscrupulous or inexperienced suppliers to make deals for products they do not actually have. Prestige Ameritech, the largest maker of medical face masks in the US, warned consumers on its website in late March of a proliferation of individuals using fake websites and email addresses to pose as the company or its employees. Despite the uptick in fraudulent activity, wary health care providers desperate to locate PPE for their staff may feel compelled to pursue all solicitations, hoping to avoid the scams.

Inexperienced suppliers

Newly established entities or those not previously involved in the manufacture and supply of PPE may—intentionally or unintentionally—overstate their output capacity or underestimate the challenges of meeting unprecedented demand for their products. A relative lack of experience raises red flags for potential purchasers in a time when prompt receipt of functional goods is vital.

Reputational damage

Organizations, particularly private companies, have faced scrutiny from within their organizations and from the media for perceived failures to protect employees. Negative consumer sentiment could have a carry-over effect on these organizations, damaging their reputations and brand integrity when they resume normal operations. When an unvetted supplier fails to timely provide the PPE that is critical to the safety employees, this issue may be exacerbated.

Legal liability

Some attorneys predict that the post-COVID-19 landscape will be fertile ground for lawsuits. Health care providers and other organizations may face claims that they did not take, or took too long to implement, proper precautions to protect employees, customers, patients, and even shareholders. Companies that decide to forego vetting procedures on their suppliers may be more susceptible to lawsuits.

Foreign Corrupt Practices Act implications

US health care providers turning to foreign suppliers to obtain PPE, perhaps for the first time, should be aware that some countries operate state-owned entities ("SOEs") involved in the production of PPE. In addition, SOEs may have ownership stakes in private companies in other countries. Contracting with such companies creates potential exposure to violations of the Foreign Corrupt Practices Act, which may be unfamiliar territory for some.

Closing Thoughts

Deloitte's Corporate Intelligence Services can help organizations develop a flexible due diligence plan that acknowledges the need for quick decision making while still delivering meaningful intelligence that can help organizations identify potentially fraudulent or untrustworthy business relationships.

For more information, contact

John Leonard
Managing Director
Deloitte Financial Advisory Services LLP
Tel: +1 212 436 4292
jleonard@deloitte.com

Erin Taack
Senior Manager
Deloitte Financial Advisory Services LLP
Tel: +1 615 664 1273
etaack@deloitte.com

Endnotes

1. https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control
2. Ibid.
3. https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
4. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization