

Considerations for Assessing the Viability of a Supplier Lead on PPE Products

Since the onset of the pandemic, we have mobilized our workforce towards one goal: finding alternate approaches to securing personal protective equipment (PPE) for HealthTrust members. Our sourcing teams in the U.S. and China have searched the globe for solutions to PPE shortages. HealthTrust understands the urgency of securing PPE products, but we also feel it is important to ensure products selected are efficacious and meet the appropriate clinical standards necessary to protect caregivers and patients, as well as FDA Emergency Use Authorizations.

After pursuing more than 1,600 leads, our experience has been that many companies/individuals claiming to have access to PPE have been unable to validate the products to ensure they meet appropriate standards and/or government/regulatory requirements. Therefore, we encourage all members to exercise due caution when evaluating and selecting products and sources. Given our sourcing expertise and operator-informed perspective, we offer the following guidance to members who may be approached by manufacturers, distributors, brokers or agents offering to help you secure PPE during these uncertain times.

If talking to a **manufacturer**, make sure you understand their competencies and capabilities. Basic questions to ask may include:

1. What is your history of producing medical supplies?
2. How much effort will be required to convert your current operation to produce PPE items?
3. Is your company licensed, registered or approved by the FDA or other regulatory agencies for the specific product being offered, or for any medical product?
4. Can you scale to the level of production to support my needs?
5. What quality/efficacy controls do you have in place?

If the company is a **distributor**, you may want to ask:

1. Are you an authorized distributor for this specific product/manufacturer?
2. Are you purchasing directly from the manufacturer or through a third party?
3. If you buy direct from the manufacturer, can you provide me the manufacturer contact so that I can confirm you are authorized?
4. If you buy through a third party, who is it and how can you validate the product you are securing is authentic? For example, is the third party an authorized distributor of the original manufacturer; can they provide any chain of custody documentation on the products; can they offer any evidence related to how the product was stored (if relevant for the product category); can they provide lot numbers, and is there a way to validate the lot number?

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A **broker or agent** seeks to connect a buyer and a seller as an intermediary. The broker typically does not have possession of or direct access to product, and in some cases, multiple brokers may be involved in the selling of the same product. Very often, the broker is not familiar with regulatory requirements or standards applicable to a product. The further removed a broker/agent is from the actual manufacturer, often the higher the risk. Always ask:

1. Has the product already been produced or is it pending future production?
2. Where is the product located?
3. Do you work directly with the manufacturer or through another agent/intermediary?
4. If you work with the manufacturer, can you provide the name and contact information of the manufacturer?
5. What are the payment terms and conditions? Will you allow the product to be shipped to me or other mutually agreed location so that we can inspect before accepting the delivery and making payment?

Beware of any manufacturer, distributor, broker or agent that is not fully transparent. Due diligence should include:

- a) Validate whether the product is FDA approved (including, as applicable, under the FDA Emergency Use Authorizations). Many companies will refer to their product being FDA registered. Please note that FDA registration is not the same as FDA approved.
- b) Validate the CE Certification they provide. A CE Certificate should be done through an approved notifying body. Many CE Certificates we have received are not from approved notifying bodies and cannot be validated.
- c) In some cases, you may need to review independent third party testing reports to ensure the product meets the testing standards necessary to perform as needed.
- d) And of course, basic research on the company such as when it was founded, what their credit rating is and when their website was formed are all easy checks that could turn out to be red flags.
- e) Ensure that the individuals or entities do not appear on the OIG Exclusions Database (<https://exclusions.oig.hhs.gov/>).

Our sourcing experts are happy to work with you to evaluate supplier leads that could result in viable solutions to PPE shortages. Please contact **HealthTrust Member Support at 855-623-0462** seven days a week (7 a.m. – 8 p.m. CT), or speak to your HealthTrust account director.

Finally, if you think you are a victim of a scam or attempted fraud involving COVID-19, you can report it to federal authorities at the [National Center for Disaster Fraud](#) Hotline at 866-720-5721 or via email at disaster@leo.gov.

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