HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

FAQ And Checklist To Vet Suppliers

When medical products are constrained or in short supply, offers from unknown sources fill inboxes across the supply chain. Navigating these offers is difficult, especially during times of crisis. Medical product distributors have experience vetting suppliers and can be a resource.

What are the business risks associated with using an unfamiliar source?

The most critical risk is receiving unapproved, unsafe products. Providers report having received incorrect product, poor quality items, or counterfeit items that fail to protect staff from disease risks. Other risks include losing money and wasting staff time.

What can I do to minimize the risk of sourcing from unknown vendors?

Many healthcare providers trust their distributor partner to vet new sources. Those who choose to do their own sourcing should keep in mind that offers that sound too good to be true often are. If considering an unfamiliar source, do basic due diligence such as checking references and securing a sample. A recommended checklist is on the back.

Are there resources to help me figure out if a new source is legitimate?

Many manufacturers post helpful end-user purchasing information on their web sites, such as lists (or hotlines) to confirm authorized sellers, the models and list prices at which their products may be sold, and descriptions of the intended use, labeling, packaging, and certification of various personal protective equipment (PPE) supplies. Other resources that can help determine if a vendor is authentic:

- **Office of Inspector General Exclusions Program** identifies federally excluded entities
- **System for Award Management** tracks organizations able to do business with federal government
- **Food and Drug Administration (FDA) Establishment Registration & Device Listing** identifies companies and the U.S. Agent registered with the FDA
- **FDA 510(k) Database** identifies if company provided proof to the FDA that its products are safe

For PPE Specifically:

What is the difference between credible commercial distributors and opportunistic brokers?

• ***Distributors*** typically serve as a single source through which providers can buy PPE and other medical products critical to everyday operations. Distributors vet the suppliers they represent. They generally take ownership of and stock the products they sell, offer a range of logistics services, and usually have long-term business relationships with their provider customers.

• ***Brokers*** facilitate deals between sellers and buyers and often solicit bids from potential purchasers. Brokers do not take ownership of products, are focused on individual transactions, and usually do not have long-term relationships with healthcare product sellers or buyers.

What risks are associated with a brokered transaction?

This transaction type is ripe for price gouging, especially in times of high demand. Brokered deals force buyers to bid against buyers, pushing prices up and driving goods to the highest bidder without consideration to where product is most needed. Additionally, because a broker does not accept title to products, industry acceptable transportation controls are not guaranteed. This creates an increased risk for shipments being lost or damaged in transit. Some brokers produce counterfeit versions of branded-product with fraudulent product registrations, certificates, and/or test reports that do not meet federal quality standards. Some use official looking but misleading logos and brands in their communications.

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Supplier Vetting Checklist

Reliable and experienced suppliers can provide rapid and verifiable responses to the questions below.

- ✔ Are you able to demonstrate proof of a variety of FDA and/or other agency regulatory compliance? This includes, but is not limited to:
  - Product Clearances/Approvals: The type and class of medical product will determine this – examples include:
    - » FDA 510k or Pre-Market Approval (PMA)
    - » FDA Emergency Use Authorization (EUA)
    - » National Institute for Occupational Safety and Health (NIOSH) approval (for surgical respirators NIOSH and FDA have joint oversight, other respirators are regulated by NIOSH)
    - » Environmental Protection Agency (EPA) (EPA regulates cleaning and disinfectant products and has memorandum of understanding (MOU) with FDA for these products)
    - » ISO 9001 2015 and/or ISO 13485 Certification from International Organization for Standardization (ISO)
  - Registered Facility Location(s)
  - Applicable FDA # for Site(s)
  - Global Unique Device Identification Database (GUDID) Participation
  - Meet product attribution requirements such as manufacturing date, expiration date, UDI where required.
- ✔ Are you able/willing to host a site visit for potential commercial or public sector partner?
- ✔ How long have you or your source manufactured medical supplies?
- ✔ Can you provide information on inventory? *(Industry recommends that the value of inventory of request items or component parts be identified by kit. Inventory turns by item or kit. If multiple sites, information must be provided by location.)*
- ✔ Can you provide photographs of locations and products?
- ✔ Can you offer healthcare industry references? *(Industry recommends sourcing references as well as customer/clinical references should be utilized.)*
- ✔ Can you provide samples of products from multiple lots? *(Commercial market distributors often share samples with multiple provider customers and ask for feedback and evaluation of new supplier's product.)*
- ✔ Can you provide copies of customer invoices with specific products listed sold to MedSurg dealers or end-users
- ✔ Can you provide a copy of your quality manual?
- ✔ Can you provide the company's W-9 and applicable business licenses for the products in the states supplied by location?
- ✔ Can you provide documentation of financial health? *(Commercial distributors often request a supplier share audited financials and/or D&B depending on type and size of company.)*
- ✔ Have you ever had to conduct a FDA recall? If so, for how long?
- ✔ When was your most recent FDA inspection? What was result? *(Industry recommends requesting 483 report compliance as appropriate and applicable. This may be optional depending on the product/supplier.)*
- ✔ Do you have an International Organization for Standardization (ISO) registration number?
- ✔ Can you provide product information such as the following:
  - Lab reports
  - Literature/clinical studies
  - Product features and attributes
  - GUDID information
  - Country of origin
  - Trade Agreement Act (TAA) compliance