

Repurposing operations to help with COVID-19 supplies

Technical Capabilities from Liberty Mutual Insurance

Highlights:

- Transitioning your operations raises complex questions
- [The Public Readiness and Emergency Preparedness Act \(PREP Act\)](#) can help protect your business, but consult your legal advisors to make sure your operation qualifies
- Other manufacturers might be able to give you peer-to-peer guidance

Manufacturers are a crucial part of enabling our healthcare workers to do their jobs safely. While answering the call to produce masks, ventilators, and other COVID-19-related items may be the right business decision for your company, it's no small feat to overhaul your operation.

We're here to help you think through the potential impacts of repurposing your business operations. The situation is changing by the minute, and we can help answer your questions and give guidance to help reduce the risks of transition.

What to consider when transitioning your operation

As you change operations, new or unexpected exposures can be created. Before beginning to manufacture products to help combat the COVID-19 pandemic, consider the following elements:

- If the product you are making is a medical device, submit an authorization registration to have the [device listed](#) on the FDA database.
- Determine whether the product you are making is backed by tort immunity under the PREP Act. It is covered if it falls within the definition of a "covered countermeasure" as spelled out by the Secretary of Health & Human Services (HHS) in a declaration published in the [Federal Register](#), and referenced documents.
 - If you're planning to make medical use masks, the U.S. Food and Drug Administration (FDA) explains which masks are acceptable [here](#) and [here](#).
 - If your legal counsel does not believe PREP Act immunity applies, you can also try to limit your risk by ensuring your contracts have a visible disclaimer you are selling the products without warranty in an "as is" condition. Do not overstate any COVID-19 protection. Ask for defense and indemnity protection from the ultimate purchaser.
- Perform a literature search for related standards using this [FDA standards database](#).
- Consult with current manufacturers of related products you wish to replicate or modify to be sure you are within your expertise and capabilities.
 - For example, Ford and General Motors consulted with GE Healthcare and Ventec engineers to learn the appropriate ways to fabricate ventilators on a wider scope.
- Clarify the regulatory standards your operations are following by referring to [ASTM Standards and COVID-19](#).
- Review specific warnings/labels and post-sale communications that should be included with the product(s). For example, if not for resale, identify that on the product label.
- Apply your current recall/traceability programs for newly manufactured products. Consult with legal counsel to determine the best approach based on the type of product being manufactured.

Our dedicated [Consulting Center](#) (1-866-757-7324) is available 9 a.m. – 7 p.m. ET Monday through Friday to help with your risk control needs.

Additional resources

[Best Product Safety Practices for Manufacturers](#)

[Best Practices for Motor Vehicle Operations](#)

[ASTM Standards and Covid-19](#)

[FDA Recognized Consensus Standards \(Database Search Tool\)](#)



Looking for more comprehensive safety information? As a policyholder, you have exclusive access to risk control tools and resources through Liberty Mutual SafetyNet™ – visit lmi.co/safetynet

For more information, contact your local service director or the Risk Control Consulting Center. Email anytime – RCConsultingCenter@LibertyMutual.com – or call 1-866-757-7324, Monday – Friday, 9 a.m. to 7 p.m. eastern.



Your safety and well-being are our primary concern. These suggestions are general in nature, so please ensure that any activities you contemplate comply with all federal, state, and local COVID-19 orders impacting your facilities or operations as well as CDC guidelines for social distancing, hygiene, and other recommended best practices.

Our risk control services are advisory only. We assume no responsibility for: managing or controlling customer safety activities, implementing any recommended corrective measures, or identifying all potential hazards. No attempt has been made to interpret any referenced codes, standards, or regulations. Please refer to the appropriate government authority for interpretation or clarification.

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