

Urgent Need for Medical Supplies

March 27, 2020 - The State of Washington is seeking to fill severe shortages of specific infection-control products and other healthcare supplies listed below.

How can Washington State Manufactures Help?

If you are **willing to re-purpose your manufacturing operations** for the production of PPE supplies, companies should contact; covidmanufacturing@commerce.wa.gov.

If you **have a product to sell or donate**, the Department of Enterprise Services (DES) is working to purchase or arrange bulk donations of specific PPE and infection-control products identified by the Department of Health and in coordination of the Governor's Office. [Impact Washington](#) is working with them once the equipment need confirmed by interfacing and coordinating with the manufacturer.

If you are a distillery who wants to make hand sanitizer bottled in 750 ml or 1-liter plastic bottles-

covidmanufacturing@commerce.wa.gov

DES Is seeking the following products:

- Disposable gowns
- Coveralls
- N95 masks
- Surgical Procedure Masks
- Face shields
- Gloves
- Powered Air Purifying Respirators (PAPR)
- PAPR hoods
- PAPR filters
- Comfort Strips (Max Ari 2000-201)
- Li-Ion Battery
- Small (Max Ari 200-36T)
- Impermeable Barriers
- Sanitizing/Disinfectant Wipes
- Hand Sanitizer Bottles
- Hand Sanitizer Refills
- Cleaning Solution Spray
- Digital thermometers (forehead)
- Disposable Thermometers
- Disposable Stethoscopes

The FIRST STEP for manufacturers who are able and willing to work with the state for distribution through their channels, they should record what they have on this [website form](#):

Please note that the state is taking adequate precautions to prevent further spread of disease or virus, therefore:

- All Donated Product must be in its original packaging, untampered and undamaged
- All Donated Product must be within its shelf life (not expired)
- All Donated & Produced Product must be FDA-approved – see *additional guidance on FDA Approval below*

Other Offers and Inquiries

Inquiries regarding other items, including the following, should be directed to covidhelp@mil.wa.gov.

- Offers of PPE that are not on the list specified above
- Suggestions for other equipment or technology
- Ideas for involving community organizations in gathering or making items
- Views from non-manufacturers on how to produce additional items

Guidance on Production of PPE from the FDA Approval (RRF2591-110526)

Specific to the manufacturing of PPE in response to the COVID-19 outbreak, the FDA is interested in hearing from manufacturers who may be able to help mitigate potential shortages of the below items by increasing U.S. availability of them.

The FDA is collaborating with manufacturers of personal protective equipment (PPE) to help facilitate mitigation strategies related to the COVID-19 outbreak. The FDA's door is open, and they are available to collaborate with stakeholders on the following items:

- Surgical masks (FXX)
- Surgical mask with antimicrobial/antiviral agent (OUK)
- Pediatric/child facemask (OXZ)
- Surgical gowns (FYA)
- Isolation gowns and surgical apparel accessories (FYC, LYU, OEA)
- Surgical suits (FXO)

To help alleviate supply pressures, the FDA may consider expedited review of manufacturing site changes or premarket submissions. Please note that the FDA is not waiving requirements; they are fast-tracking on a case by case basis.

All manufactures must comply with all [CFR Title 21](#).

At a high level, the steps to achieve FDA approval generally are:

- 1) Ensure you have a compliant Quality Management System
- 2) Develop the product you would like to submit while maintaining required records
- 3) Submit the product to an independent FDA certified lab for testing to [ASTM Standards](#)
- 4) Submit product to FDA for approval

Manufacturers may email FDA at deviceshortages@fda.hhs.gov. This email is carefully monitored and has proven to be a valuable resource thus far in helping FDA mitigate potential supply chain disruptions.

To facilitate a rapid response to such inquiries, please go to the link below to get additional information and to see an example of information that FDA would find helpful to have initially. <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns>