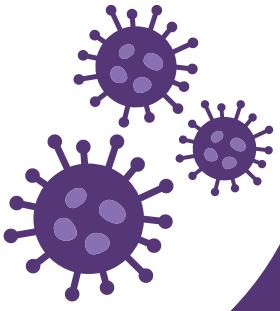

COVID-19 Response Assistance

What You Should Know and How You Can Help

Governor Parson has called on businesses to produce needed supplies related to COVID-19. Missouri needs companies to help in addressing the need for medical supplies and Personal Protective Equipment (PPE).

COVID-19 MEDICAL SUPPLIES GUIDELINES

Manufacturers interested in making these supplies, please review the detailed information below first, including new guidance from the FDA and CDC. You will likely be required to obtain federal certification to begin manufacturing and sales for most of the critically needed products. FDA is constantly updating their requirements. Manufacturers should ensure they are following the most recent guidelines.

Ventilators

- High acuity, invasive, portable, battery operated ventilators
- The FDA released new guidance that allows more manufacturers to make ventilators at this time.
- The agency is allowing for device modification, and the utilization of ventilators intended for other environments.
- Example models: Puritan Bennet 840, Viasys Avea, Drager Evita, GEinvent, Maquet Servo-I, Hamilton G5, GE Carescape

PERSONAL PROTECTIVE EQUIPTMENT

N95 Respirators (hospitals)

- There are two types of respirators that are appropriate for healthcare workers with close contact with COVID-19 patients: 1) N95 Respirators; and 2) Surgical N95 Respirators.
- N95 Respirators (approved by NIOSH under 42 CFR Part 84) are appropriate for healthcare settings where only protection from patient generated aerosols is required.
- KN-95 must meet NIOSH and/or EU standards and be CE certified.
- Surgical N95 Respirators are the appropriate device in the healthcare setting when both aerosol and barrier protection (i.e., splash or sterile field) are needed and must be approved by both NIOSH as a FFR (42 CFR Part 84) and FDA as Class II Medical Device (21 CFR 878.4040).
- FDA tests: Fluid resistance (ASTM F1862), flammability, and biocompatibility.

PERSONAL PROTECTIVE EQUIPTMENT CONT.

Medical (surgical) masks

- Surgical masks must be FDA approved under 21 CFR 878.4040 as Class II Medical Devices.
- Manufacturing standard: ASTM F2100 – 19
- ASTM F2100 Level 1 standards for material quality apply in hospital/ICU settings
- Fluid Resistance with synthetic blood: 80mmHg
- Differential pressure: <4.0mmH2O
- Equal to or greater than 95% Bacterial Filtration Efficiency (BFE)Submicron Particle Filtration (PFE) @ 0.1u, %: ≥95%
- Flammability: Class 1
- Folds in mask expand for full coverage from top of nose to underneath chin

Exam Gloves

- Non-sterile, disposable patient examination gloves are appropriate for care of COVID-19 patients.
- Regulated by FDA: FDA21 CFR 880.6250 (non-powdered patient examination glove)
- Manufacturing standard: ASTM D6319 for powder-free nitrile gloves, ASTM D3578 for powder-free latex gloves

Gowns (medical), disposable with elastic wrists

- Non-sterile, disposable patient isolation gowns are appropriate for care of COVID-19 patients
- A surgical gown is regulated by the FDA as a Class II medical device that requires a 510(k) premarket notification. Surgical gowns can be used for any risk level (Levels 1-4).
- FDA standards for gowns can be reviewed here.
- Four defined levels of protection tested to meet ANSI/AAMI PB70:

LEVEL 1 — Minimal risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit.

LEVEL 2 — Low risk, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab.

LEVEL 3 — Moderate risk, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases.

LEVEL 4 — High risk, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne).

PERSONAL PROTECTIVE EQUIPTMENT CONT.

Eye/face shields

- Must meet ANSI Z87.1 for splash protection

Goggles

- Must meet ANSI Z87.1 for splash protection

Biohazard Bags (Regulated Waste)

- Must meet DOH requirements for the collection of Regulated Medical Waste (RMW) under Title 10 part 70-2.2
- Must meet DOT requirements for the transportation of RMW under 49 CFR 173.197 (e)
- Must meet OSHA requirements under 29 CFR 1910.1030(g)(1) (i)
- Red plastic bag, of sufficient strength
- Cannot exceed a volume of 46 gallons, must pass tests prescribed for tear and impact resistance under ASTM D 1922 and ASTM D 1709 respectively. Must meet a tear resistance of 480grams in both parallel and perpendicular planes with respect to length of the bag and an impact resistance of 165 grams
- Marked with a biohazard symbol

SPECIFICATIONS

You can find the specificaitons for medical supplies here:
https://www.aha.org/initiativescampaigns/2020-03-26-100-million-mask-challenge-manufacturers

CONTACT

Once you have started manufacturing PPE let us know at ded.mo.gov/howtohelp.

For any question's contact missourippe@ded.mo.gov