HHS COVID-19 March 31, 2020 Update

How is FEMA adding Critical Supplies to the Supply Chain? Right now, FEMA is expediting movement of critical supplies from the global market to medical distributors in various locations across the U.S. Each flight contains critical personal protective equipment (PPE), to include gloves, gowns, goggles, and masks in varying quantities.

Four strategies to address Supply Chain needs are being pursued concurrently:

1. **Preservation** to limit unnecessary use of PPE and other supplies.
2. **Acceleration** of industrial manufacturing is required to help meet the urgent demand placed on the market.
3. **Expansion** of the industry is taking place.
4. **Allocation** of critical resources based on data-informed decisions.

On the **Acceleration**:

- FEMA is expediting movement of critical supplies from the global market to medical distributors in various locations across the U.S.
- As an example of this effort, FEMA coordinated an air bridge for flights from Asia beginning Sunday, March 29 which delivered 80 tons of much needed PPE supplies to New York, New Jersey and Connecticut.

**FEMA Delivering 80 Tons of PPE to NY, NJ and CT**
• The second flight landed in Chicago this morning. Ohio is likely tomorrow. FEMA has scheduled additional flights and is adding more daily.
• Each flight will contain critical PPE (gloves, gowns, goggles, and masks) in varying quantities. FEMA will not have detailed visibility on the amount of PPE until the flights are loaded overseas.
• Upon arrival, PPE will be provided, in varying quantities, first to medical distributors in areas of greatest need; then, the remainder will be infused into the broader U.S. supply chain. Prioritization will be given to hospitals, health care facilities, and nursing homes around the country.
• Additionally, in some cases, the federal government may purchase some of the supplies to be used to replenish the Strategic National Stockpile (SNS) or to provide to states with any identified and unmet needs.
• To address the anticipated ventilator shortage across the nation, the task force has implemented a similar strategy, leveraging the strengths of the commercial industry including numerous vendors, such as General Electric, Phillips, Medtronic, Hamilton, Zoll, ResMed, Hillrom and Vyair, to produce 20,000 ventilators over the next two months with the potential to add 100,000 by end of June. This represents a significant increase in velocity as the normal annual market is 30,000 per year.
• As a reminder, to expedite purchasing, FEMA issued a request for quotation for vendors who have needed medical equipment and supplies to sell to the agency.

Admiral Brett Giroir & Surgeon General Jerome Adams Release Letter on Optimizing Ventilator Use: Last night, the Assistant Secretary of Health and US Surgeon General issued an open letter on strategies for optimizing ventilator use including use of guidance on co-venting. In the letter, they note that ventilation of two patients with one ventilator should only be considered as an absolute last resort, but for those clinicians in crisis situations, the letter outlines how ventilator splitting can be performed strictly for two patients who are both either infected or free of the virus. We know that practices like this are currently being used in some hospitals. In that vein, we strive to provide additional information to support patient-provider decision making during times of crisis standards of care. We recognize that these decisions must be made on an individual institution, care-provider, and patient level. This is a reflection of how HHS and FEMA are working with multiple partners: healthcare systems, academic institutions, professional medical societies, and the National Academies of Science, Engineering and Medicine to develop crisis standards of care strategies for ventilator support when resources are limited.

Expanding Availability of PPE and Sterilizers and Disinfectant Devices: FDA issued guidance to help expand the availability of surgical apparel for health care professionals, including gowns, hoods, and surgeon’s and patient examination gloves during the pandemic. They also released guidance to expand the availability and capability of sterilizers, disinfectant devices and air purifiers during the pandemic. The devices include those intended to make devices sterile, kill pathogens or other microorganisms and kill pathogens or microorganisms in the air. This policy reflects FDA’s commitment to ease burdens on health care providers and facilities as they face COVID-19.
CMS Granting Key Flexibilities - Worth Including Twice: Yesterday, CMS released an array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. These temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The new rules allow hospitals and health systems to deliver services at other locations to make room for COVID-19 patients needing acute care in their main facility. CMS also posted a complete summary of the flexibilities provided to all physicians and clinicians to help clarify current allowable and billable practices. CMS also approved two additional Section 1135 waivers today, bringing the total of approved waivers to 40 states.

Granting Financial Relief for Medicare Providers – Worth Repeating: Over the weekend, CMS provided financial relief to Medicare providers by expanding their accelerated and advance payment program to help ensure that they have resources needed to combat COVID-19. Accelerated and advance Medicare payments provide emergency funding and addresses cash flow issues based on historical payments when there is disruption in claims submission and/or claims processing. CMS is expanding the program for all Medicare providers throughout the country during the public health emergency related to COVID-19. The payments can be requested by hospitals, doctors, durable medical equipment suppliers and other Medicare Part A and Part B providers and suppliers.

Updating Guidance for Labs: CDC updated their laboratory guidance for handling and processing specimens associated with COVID-19 to include environmental specimen testing guidance related to procedures that concentrate viruses.

Determining if You Are At Higher Risk for Severe Illness: CDC updated their webpage for people who are at higher risk for severe COVID-19 illness.

Providing Guidance for Healthcare Professionals: CDC added to their FAQ document for healthcare professionals additional information on drugs and investigational therapies to address common questions and misperceptions on available and approved drugs to treat COVID-19. CDC also released guidelines and a decision algorithm for how to guide care advice and messages with evaluating and triaging potential patients.

Obtaining Funding from FEMA for Emergency Medical Care Activities: The FEMA COVID-19 Emergency Protective Measures Fact Sheet included a list of eligible emergency medical care activities. This fact sheet provides additional guidance related to the eligibility of emergency medical care activities as an emergency protective measure under the Emergency Declaration and any Major Disaster Declaration authorizing Public Assistance (PA) for COVID-19.

Addressing Questions on Non-Congregate Sheltering: Non-congregate sheltering may be necessary for health and medical-related needs, such as isolation and quarantine of certain populations resulting from the public health emergency. FEMA released an FAQ document on non-congregant sheltering and how states can apply to receive approval for them.
Preparing Outpatient Hemodialysis Facilities for COVID-19 Patients: CDC released updated guidance for Infection Prevention and Control for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities. This information is provided to clarify COVID-19 infection prevention and control (IPC) recommendations that are specific to outpatient hemodialysis facilities. Recommendations are listed for screening and triage of patients.

Addressing Considerations for Clinical Trials: The FDA issued an updated guidance, Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, with an appendix adding questions and answers on this subject. This guidance is intended for industry, investigators and institutional review boards and was issued because we recognize that the COVID-19 pandemic may impact the conduct of clinical trials of medical products, including drugs, devices and biological products.

Granting Flexibilities to ACF Recipients: In a memo to all of their grantees, ACF shared information to assure their grantee and recipient communities that to the extent possible they will provide short-term relief for administrative, financial management, and audit requirements in their human services programs.

Ensuring Providers Can Practice at Health Centers and Free Clinics: HRSA has released information on updated Federal Tort Claims Act policies for providers in health centers and free clinics to enable them to treat patients in these settings in an effort to prevent, prepare or respond to COVID-19.

Supporting Governors in Crisis States: The President released a memo that provides additional support to Governors in Connecticut, Illinois, Massachusetts and Michigan, allowing them to use the National Guard with 100% federal support.

In closing, a morning headline caught my eye, “Agencies like CMS and FDA are Moving at Warp Speed.” Indeed, for many of you, the concept of regulatory bodies moving at “warp speed” to address this crisis is rather incredible. We are extremely proud of how so many across HHS and the Administration are moving mountains to get solutions in place. Yesterday, I tipped my hat to the private sector’s innovation in helping the country get through this. Today, we acknowledge and thank the public servants who are clearing the decks and problem-solving at “warp speed.”

The President’s Coronavirus Guidelines for America

For background and the most up-to-date information, please visit the Centers for Disease Control and Prevention Coronavirus Disease 2019 website: HERE

U.S. Department of Health and Human Services:
What you should know:

- Workplace, School, and Home Guidance
- People at Risk for Serious Illness from COVID-19
- How COVID-19 Spreads
- Symptoms
- Steps to Prevent Illness
- Frequently Asked Questions
- What to Do If You Are Sick with COVID-19
- Stigma Related to COVID-19
- Facts about COVID-19
- Information for People at Higher Risk and Special Populations
- Communication Resources

Situation Updates:

- Situation Summary
- Cases in the U.S.
- Global Locations with COVID-19
- Risk Assessment
- CDC in Action: Preparing Communities

Information for Businesses:

- Interim Guidance for Businesses and Employers
- Information for Communities, Schools, and Businesses
- Environmental Cleaning and Disinfection Recommendations – Community Facilities
- SBA: COVID-19 Resources
- DOL: Guidance for Preparing Workplaces for Coronavirus
- DOL: OHSA Resources for Workers and Employers on COVID-19
- WHO: Get Your Workplace Ready for COVID-19
- CISA: Risk Management for COVID-19
- EPA: Disinfectants for Use Against COVID-19
Information for Travel and Transportation:

- Information for Travel
- Guidance for Ships
- Guidance for Airlines and Airline Crew
- State: Travel Advisories
- State: Traveler’s Checklist
- State: Smart Traveler Enrollment Program
- DOT: FAQs from FTA Grantees Regarding COVID-19

Information for Healthcare Providers, First Responders, and Research Facilities:

- Information for Healthcare Professionals
- Resources for State, Local, Territorial and Tribal Health Departments
- Resources for Healthcare Facilities
- Infection Prevention and Control Recommendations for Patients with COVID-19 or Persons Under Investigation in Healthcare Settings
- Information for Laboratories
- Resources for First Responders
- Guidance for Public Health Professionals Managing People with COVID-19 in Home Care and Isolation Who Have Pets or Other Animals
- FAQs and Considerations for Patient Triage, Placement and Hospital Discharge
- Guidance for Homeless Shelters
- Guidance for Hemodialysis Facilities
- CMS: Information on COVID-19 and Current Emergencies
- CMS: Guidance for Hospice Agencies
- CMS: Emergency Medical Treatment and Labor Act Requirements and Implications Related to COVID-19
- CMS: FAQs for State Survey Agency and Accrediting Organizations
- EPA: Disinfectants for Use Against COVID-19

Information for Law Enforcement:

- What Law Enforcement Personnel Need to Know
- Bureau of Prisons COVID-19 Resources

Information for Families and Households:

- Information on COVID-19 for Pregnant Women and Children
- Interim Guidance for Household Readiness
- Environmental Cleaning and Disinfection Recommendations for U.S. Households
- Guidance for Preventing the Spread of COVID-19 in Homes and Residential Communities
• FAQ: COVID-19 and Children
• EPA: Disinfectants for Use Against COVID-19

**Information for Schools and Childcare Providers:**

- Interim Guidance for Administrators of U.S. Childcare Programs and K-12 Schools
- Resources for Institutes of Higher Education
- Environmental Cleaning and Disinfection Recommendations – Community Facilities
- USDA: USDA Makes It Easier, Safer to Feed Children in California Amid Coronavirus Outbreak
- DOEd: Resources for Schools and School Personnel
- EPA: Disinfectants for Use Against COVID-19

**Information for Community Events and Gatherings:**

- Interim Guidance for Mass Gatherings and Large Community Events
- Interim Guidance for Community- and Faith-Based Organizations
- EPA: Disinfectants for Use Against COVID-19

**Agency Resources and Information:**

- U.S. Department of Health and Human Services
- Centers for Medicare and Medicaid
- U.S. Food & Drug Administration
- U.S. Department of Agriculture
- U.S. Department of Defense
- U.S. Department of Education
- U.S. Department of Energy
- U.S. Department of Homeland Security
- U.S. Department of Labor
- U.S. Department of State
- U.S. Department of Veterans Affairs
- U.S. Environmental Protection Agency
- U.S. Small Business Administration