From: HHSRegion7 Update < HHSREGION7 UPDATE@LIST.NIH.GOV > on behalf of HHS Region 7 (OS/IEA)

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Sent: Wednesday, April 1, 2020 10:24:29 AM

Subject: HHS Region 7 COVID-19 Update- April 1, 2020



# Iowa | Kansas | Missouri | Nebraska

Dear Colleague,

HHS alongside our federal partners are continuing to work with state, local, tribal and territorial governments to execute a whole of America response to fight the COVID-19 pandemic and protect the public, with the health and safety of the American people as our top priority.

Many of you are working on the supply chain issues or have had questions about getting supplies to needed areas. On that topic, I would like to highlight some very encouraging developments.

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.

<u>Four strategies</u> to address Supply Chain needs are being pursued concurrently:

- 1. **Preservation** to limit unnecessary use of PPE and other supplies.
- 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** piece, I want to highlight the following updates:

- 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 <u>request for</u> <u>quotation</u> 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 <u>expand the availability of surgical apparel</u> for health care professionals, including gowns, hoods, and surgeon's and patient examination gloves during the pandemic. They also released guidance to <u>expand the availability and capability of sterilizers, disinfectant devises and air purifiers</u> 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 - 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 – 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 <u>updated their laboratory guidance</u> 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 <u>FAQ document on non-congregant sheltering</u> 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 <u>health centers</u> and <u>free clinics</u> 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 <u>released a memo</u> that provides additional support to Governors in Connecticut, Illinois, Massachusetts and Michigan, allowing them to use the National Guard with 100% federal support.

Best regards,

#### Wm. Jeff Kahrs

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