

March 31, 2020

# HHS CMS Announces New Waivers, Accelerates Clinical Trials; FDA Approves Rapid Test; FEMA Launches Project Airbridge to Move PPE

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Michael Best Strategies LLC

### CMS WAIVERS ANNOUNCED

Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge

CMS today is issuing an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the COVID-19 pandemic. **CMS's waivers and flexibilities will permit hospitals and healthcare systems to expand capacity** by triaging patients to a variety of community-based locales, including ambulatory surgery centers, inpatient rehabilitation hospitals, hotels, and dormitories. Transferring uninfected patients will help hospital staffs to focus on the most critical COVID-19 patients, maintain infection control protocols, and conserve personal protective equipment (PPE).

For additional background information on the waivers and rule changes, available [here](#).

For more information on the COVID-19 waivers and guidance, and the Interim Final Rule, please go to the CMS COVID-19 flexibilities webpage [here](#).

### Executive Branch COVID-19 Updates

See below for some of the critical new actions taken in recent days to combat the coronavirus and support our nation's incredible healthcare professionals.

- The President announced he is extending CDC guidelines to slow the spread of the virus.

- FEMA launched Project Airbridge to help quickly airlift critical supplies across the country.
- The FDA gave emergency approval for a new rapid test that can deliver results in as little as 5 minutes.
- The FDA gave emergency approval to a new system to sterilize N95 masks, helping hospitals get the most use out of their masks.
- The FDA approved the emergency use of convalescent plasma treatments for seriously ill coronavirus patients.
- CMS issued sweeping regulatory changes to help increase hospital capacity, rapidly expand the healthcare workforce, and cut paperwork so doctors can focus on patients.

### **From the White House**

- Memorandum on Providing Federal Support for Governors' Use of the National Guard
- President Trump and Members of the Coronavirus Task Force Hold a Press Conference – 3/30 Video
- President Trump, Vice President Pence, and Members of the Coronavirus Task Force Hold a Press Briefing – 3/29 Remarks , **and Video**
- President Trump Approves Disaster Declaration for Alabama, **Connecticut, Colorado, District of Columbia, Georgia, Guam, Kansas, Kentucky, Massachusetts, Michigan, Oregon**
- President Trump Meets with Supply Chain Distributors Remarks **(VIDEO)**
- Letter from the Vice President to Hospital Administrators
- Ivanka Trump: Emergency Relief Bill Will Help America's Small Businesses

### **HHS**

Accepts donations of medicine to Strategic National Stockpile as possible treatments for COVID-19 patients

HHS accepted 30 million doses of hydroxychloroquine sulfate donated by Sandoz, the Novartis generics and biosimilars division, and one million doses of chloroquine phosphate donated by Bayer Pharmaceuticals, for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials.

Accelerates Clinical Trials, Prepares for Manufacturing of COVID-19 Vaccines

HHS took steps today to speed the development and manufacturing of vaccines to prevent COVID-19, working with New Jersey-based Janssen Research & Development, part of Johnson & Johnson, and Moderna of Cambridge, Massachusetts.

CMS Engages America's Hospitals in Unprecedented Data Sharing

CMS sent a letter to the nation's hospitals on behalf of Vice President Pence requesting they report data in connection with their efforts to fight COVID-19.

#### OCR Issues Bulletin on Civil Rights Laws and HIPAA Flexibilities That Apply During the COVID-19 Emergency

The Office for Civil Rights (OCR) at the U.S Department of Health and Human Services (HHS) is issuing a bulletin to ensure that entities covered by civil rights authorities keep in mind their obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs, including in the provision of health care services during COVID-19.

#### CDC Statement on COVID-19 Apple App

Apple Inc. – in partnership with the White House Coronavirus Task Force and the U.S. Department of Health and Human Services, including the Centers for Disease Control and Prevention (CDC) – released an app and website that guides Americans through a series of questions about their health and exposure to determine if they should seek care for COVID-19 symptoms. Download the app here:

#### CMS Provides Financial Relief for Medicare Providers

CMS and the Centers for Medicare & Medicaid Services is announcing an expansion of its accelerated and advance payment program for Medicare participating health care providers and suppliers, to ensure they have the resources needed to combat the Coronavirus.

#### FDA Comments on CARE's Act Landmark Over-the-Counter Drug Reform and User Fee Legislation

#### FDA expedites review of diagnostic tests to combat COVID-19

The FDA is providing flexibility to labs and manufacturers to develop and offer COVID-19 tests across the U.S.

#### Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

FDA is issuing this guidance to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during this public health emergency.

#### Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency

FDA is issuing this guidance to provide restaurants and food manufacturers with flexibility regarding nutrition labeling so that they can sell certain packaged foods during the COVID-19 pandemic.

### **DHS**

#### Guidance on the Essential Critical Infrastructure Workforce 2.0

The Cybersecurity and Infrastructure Security Agency (CISA) executes the Secretary of Homeland Security's authorities to secure critical infrastructure. Consistent with these authorities, CISA has

developed, in collaboration with other federal agencies, State and local governments, and the private sector, an “Essential Critical Infrastructure Workforce” advisory list.

#### FEMA: Photos of the Whole-of-America COVID-19 Response

The Whole-of-America response to fighting the COVID-19 pandemic continues this weekend, as President Donald Trump visited the men and women aboard USNS Comfort (T-AH-20) Saturday at Naval Station, Norfolk, Va., before the hospital ship deployed to New York in support of the nation’s COVID-19 response efforts.

#### Be Like Mike VIDEO

If you've been to an area with current travel restrictions due to the coronavirus pandemic, you can still come home anytime. You'll just follow these guidelines.

#### Ongoing Actions to Respond to the Coronavirus Pandemic VIDEO

The men and women of DHS are on the front lines every day, fighting against the spread of coronavirus to protect the homeland. Here’s what we’re doing.

### **HUD**

#### COVID-19: Client Screening and Work Flow Examples

This resource contains client screening and work flow examples from Atlanta, GA and San Diego, CA.

#### Protecting Health and Well-being of People in Encampments during an Infectious Disease Outbreak

Continuums of Care should work in close consultation with their local/state public health agencies and their local/state emergency management offices to develop the strongest possible approaches to protect the health and well-being of people who are currently unsheltered.

### **DEFENSE**

#### USNS Mercy Begins Treating Patients in Los Angeles

The Navy hospital ship USNS Mercy has accepted its first patients in Los Angeles during its support of the nation's COVID-19 response efforts.

#### Partnering With the U.S. Defense Industrial Base to Combat COVID-19

The Department continues to aggressively partner with the defense industry to mitigate impacts from the COVID-19 national emergency.

#### Trump, Esper Send Off USNS Comfort to Join New York's COVID-19 Fight

The United States is at war with an invisible enemy in the coronavirus, President Donald J. Trump said from the dock at Naval Station Norfolk, Virginia, where he and Defense Secretary Dr. Mark T. Esper saw off the Navy hospital ship USNS Comfort as it left for New York City to join the response to the COVID-19 pandemic.

The USNS Comfort arriving in New York City:

#### Army Corps of Engineers Creates Alternative Care Facilities

Though the Army Corps of Engineers has done important work in the past seven days related to the coronavirus pandemic, transforming buildings into hospitals in the next two to three weeks is more important, the commander of the Corps said.

#### **VA**

#### Deploys Mobile Vet Centers to Increase Outreach during COVID-19 Outbreak

The VA began deploying Mobile Vet Center units, the week of March 16, to expand direct counseling, outreach and care coordination to Veterans in communities affected during the COVID-19 pandemic. The first of the mobile units was dispatched to various cities to include boroughs in New York City, a second unit was sent to San Francisco, followed by mobile centers going to New Orleans and Los Angeles.

#### VA to Assist New York City with COVID-19 Response

The Department of Veterans Affairs (VA) announced it is opening a total of 50 beds (35 acute care and 15 intensive care unit) to non-Veteran, non-COVID patients to help assist New York City in its COVID-19 response efforts. VA's decision comes in response to a request the department received from the Federal Emergency Management Agency after the state of New York asked FEMA for federal assistance.

#### COVID-19: Servicemembers' Civil Rights - Message from the Assistant Attorney General

"Since COVID-19 has come to our shores, active duty servicemembers and members of the National Guard and Reserve have shouldered new burdens as they work to protect our country. We owe it to them to ensure that COVID-19 does not jeopardize their economic livelihood."

For the most up-to-date information, please see the CDC's website: [www.coronavirus.gov](http://www.coronavirus.gov).

#### **CARES ACT News**

The \$2.2 trillion Phase 3 Stimulus bill finally passed the House and is being sent to the President. The 880-page measure is the largest economic relief bill in U.S. history, The bill builds upon earlier versions of the CARES Act and is intended to be a third round of federal government support in the wake of the coronavirus public health crisis and associated economic fallout, succeeding the \$8.3 billion in public health support passed two weeks ago and the Family First Coronavirus Response ACT. It is the product of negotiations between Democrats and Republicans for a bipartisan response to the crisis.

- A section-by-section of the Coronavirus Aid, Relief, and Economic Security Act
- A summary of the emergency appropriations for coronavirus health response and agency operations
- A summary of the small business provisions
- Final Text of CARES ACT

**For more information check our past alerts for a detailed summary of the bill.**

The House adjourned until next Tuesday, March 31<sup>st</sup>. Schedule still remains fluid but they will begin working on the framework for Phase 4. Reminder – the Senate is in recess until April 20<sup>th</sup>.

### **Next Steps**

Congress is expected to convene after Easter to consider a Coronavirus Phase IV bill.

**Speaker Pelosi** said Federation actions, tax code changes and additional appropriations needed to help states respond to virus impact. Fourth-phase virus legislation “will be about recovery,” the Speaker said and should address infrastructure issues including water systems and broadband. **Republican Leader McCarthy** said he would like to see the impact of what has been passed first before legislating.

### **Related People**

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