

HHS COVID-19 April 8, 2020 Update

Expanding PPE Supplies

HHS Expanding Ventilator Capacity: HHS announced the first contract for ventilator production rated under the Defense Production Act, to General Motors. GM's contract, at a total contract price of \$489.4 million, is for 30,000 ventilators to be delivered to the Strategic National Stockpile by the end of August 2020, with a production schedule allowing for the delivery of 6,132 ventilators by June 1, 2020. By rating contracts under the DPA, HHS is helping manufacturers like GM get the supplies they need to produce ventilators as quickly as possible, while also ensuring that these ventilators are routed through the Strategic National Stockpile to where they're needed most. A second contract was awarded to Philips for \$646.7 million for a production schedule allowing for the delivery of 2,500 ventilators to the Strategic National Stockpile by the end of May 2020 and a total of 43,000 ventilators to be delivered by the end of December 2020.

HHS Expanding TYVEK Suit Capacity: HHS announced an agreement with DuPont to expedite the delivery of critical personal protective equipment (PPE) needed for frontline U.S. healthcare workers responding to the COVID-19 pandemic. DuPont will deliver 450,000 TYVEK® suits to the United States from its Hanoi, Vietnam manufacturing facility this week. HHS anticipates receiving 2.25 million TYVEK suits over the next five weeks with an option to continue purchasing up to a total of 4.5 million TYVEK suits.

Treatment and Testing Updates

Pharmacists Can Now Test for COVID-19: Today, the Office of the Assistant Secretary for Health issued new guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) authorizing licensed pharmacists to order and administer COVID-19 tests that the U.S. Food and Drug Administration has authorized. This is an important step that allows for a new sector of healthcare professionals to order and administer COVID-19 tests, expanding capacity as well as increasing testing locations. The PREP Act allows for liability protections in certain cases when in a public health emergency.

Serology Test Policy: FDA released updated information on serological tests. Serology Tests are not used to diagnose COVID-19 but can play a critical role in the fight against COVID-19 by helping to identify individuals who have had and overcome an infection in the past and developed an immune response. The results can aid in determining who may donate a part of their blood called convalescent plasma as a possible treatment for those who are seriously ill from COVID-19. The FDA can authorize tests for COVID-19 under an Emergency Use

Authorization, and to date, the FDA has authorized one EUA for a serology test that is intended for use by clinical laboratories.

Resources on Chloroquine Phosphate and Hydroxychloroquine Sulfate: FDA released an FAQ document on the emergency use authorization for chloroquine phosphate and hydroxychlorquine sulfate for certain COVID-19 hospitalized patients.

FDA Resource on Coronavirus Drugs: The Center for Drug Evaluation and Research (CDER) is engaged in numerous activities to protect and promote public health during the COVID-19 pandemic, ranging from the acceleration of development for treatments for COVID-19, maintaining and securing drug supply chains, providing guidance to manufacturers, advising developers on how to handle clinical trial issues, and keeping the public informed. The information on this page includes resources on clinical trial conduct, Coronavirus Treatment Acceleration Program, Drug Shortages, Hand Sanitizers, Compounding, Fraudulent Activity, Manufacturing and Supply Chain, and Drug Registration and Listing.

Funding Updates

\$1 Billion Awarded to Health Centers: HRSA awarded more than \$1.3 billion to 1,387 health centers. HRSA-funded health centers may use the awards to help communities across the country detect coronavirus; prevent, diagnose, and treat COVID-19; and maintain or increase health capacity and staffing levels to address this public health emergency. Health centers deliver care to over 28 million people a year, regardless of their ability to pay. The award will be utilizing money appropriated from the most recently signed supplemental. HRSA also released data from their weekly survey of health centers on their COVID-19 capacity. The survey measures testing capacity, operations capacity, and PPE supply capacity.

\$34 Billion Delivered in Advanced/Accelerated Payments to Medicare Providers: As was mentioned last night in my email, CMS delivered nearly \$34 billion in the past week to the healthcare providers on the frontlines for COVID-19. The funds have been provided through the expansion of the Accelerated and Advance Payment Program to ensure providers and suppliers have the resources needed to combat the pandemic. In a little over a week, CMS has received over 25,000 requests from health care providers and suppliers for accelerated and advance payments and have already approved over 17,000 of those requests in the last week. The payments are available to Part A providers, including hospitals, and Part B suppliers, including doctors, non-physician practitioners and durable medical equipment (DME) suppliers. While most of these providers and suppliers can receive three months of their Medicare reimbursements, certain providers can receive up to six months.

Who's Getting HHS COVID-19 Grants? HHS has developed a feature that allows public viewing of all COVID-19 HHS grant and cooperative agreement awards on its website at https://taggs.hhs.gov/coronavirus. The site is a feature of TAGGS, HHS' tracking system for these awards. The new feature provides data on awards made by all HHS awarding agencies under the supplemental appropriations funded through the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, the Families First Coronavirus Response Act,

and the CARES Act, when awards are made. The site provides: a U.S. map detailing the amounts awarded by state, graphics detailing numbers of awards, amounts awarded by agency, and awards by program (CFDA number); Tables, including exportable data, with awards made by HHS using these emergency supplemental appropriation funding; and, finally, the ability to sort tables by a variety data elements (column headers).

Information for Specific Populations

IHS Expands Telehealth Services: IHS announced its expansion of telehealth across IHS federal facilities. Telehealth services means patients can stay home and reduce their risk of infection and also keep healthcare workers and others in waiting rooms and emergency departments safe from COVID-19. Six IHS sites in the Oklahoma City and Navajo Areas participated in a telehealth pilot project last week to test the system and share lessons learned; now the IHS is expanding.

Guidance for Outpatient and Ambulatory Care Settings: CDC released Interim Additional Guidance for Outpatient and Ambulatory Care Settings. This interim guidance outlines goals and strategies suggested for U.S. ambulatory care settings in response to community spread of coronavirus disease-2019 (COVID-19). This guidance includes key considerations and actions healthcare facilities can take and reflects the need to 1) minimize disease transmission to patients, healthcare personnel (HCP) and others, 2) identify persons with presumptive COVID-19 disease and implement a triage procedure to assign appropriate levels of care, 3) reduce negative impacts on emergency department and hospital bed capacity and 4) maximize the efficiency of personal protective equipment (PPE) utilization across the community health system while protecting healthcare personnel.

Considerations for Inpatient Obstetric Settings: CDC has updated their Interim Considerations for Infection Prevention and Control of COVID-19 in Inpatient Obstetric Healthcare Settings information. These infection prevention and control considerations are for healthcare facilities providing obstetric care for pregnant patients with confirmed coronavirus disease (COVID-19) or pregnant persons under investigation (PUI) in inpatient obstetric healthcare settings including obstetrical triage, labor and delivery, recovery and inpatient postpartum settings. The guidance includes information on pre-hospital considerations, during hospitalization recommendations, mother/baby contact and discharge information.

Clinical Guidance for Management of Patients with COVID-19: CDC updated their information on Interim Clinical Guidance for Management of Patients with Confirmed COVID-19. This guidance includes information on clinical presentation, clinical course, diagnostic testing, laboratory and radiological findings, clinical management and treatment, investigational therapeutics, and discontinuation of transmission-based precautions or home isolation.

Infection Control Guidance for Patients and Healthcare Workers: CMS issued new guidance on Infection Control Guidance Based on CDC Guidelines to Protect Patients and Healthcare Workers from COVID-19 that will help ensure infection control in the context of patient triage, screening and treatment, the use of alternate testing and treatment sites and

telehealth, drive-through screenings, limiting visitations, cleaning and disinfection guidelines, staffing, and more. Critically, the guidance released today includes new instructions for dialysis facilities as they work to protect patients with End-Stage Renal Disease (ESRD), who, because of their immunocompromised state and frequent trips to health care settings, are some of the most vulnerable Americans to complications arising from COVID-19.