

HHS COVID-19 April 14, 2020 Update

PPE Supplies

Expanding the Supply of Ventilators: HHS announced [five new contracts for ventilator production](#) rated under the Defense Production Act (DPA), to General Electric, Hill-Rom, Medtronic, ResMed, and Vyair, as well as two other contracts for ventilator production, to Hamilton and Zoll. In total, combined with contracts with [General Motors](#) and [Philips](#) rated under the DPA issued last week, HHS has finalized contracts to supply 6,190 ventilators for the Strategic National Stockpile by May 8 and 29,510 by June 1. The seven new ventilator contracts announced by HHS this month will provide a total of 137,431 ventilators by the end of 2020. The thousands of ventilators delivered to the Strategic National Stockpile starting this month, continuing through the spring and summer, will provide more capacity to respond to the pandemic as it evolves.

EUAs for Infusion Pumps: The FDA issued an [Emergency Use Authorization \(EUA\)](#) for the emergency use of the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES (“B. Braun Space and Outlook Pumps”) for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having COVID-19 and decrease the exposure of healthcare providers to such patients during the COVID-19 pandemic. The EUA was also issued for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System.

Testing and Treatment

Development of Immunotherapies for COVID-19 Patients: HHS will collaborate with [multiple non-government organizations on the development of convalescent plasma and hyperimmune globulin immunotherapies](#). These treatments would use antibodies against SARS-CoV-2 from COVID-19 survivors and are intended to stimulate the immune systems of people currently ill from the virus. To facilitate the development of these investigational treatments the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS office of the Assistant Secretary for Preparedness and Response, is providing support to the American Red Cross; Emergent BioSolutions of Gaithersburg, Maryland; Grifols USA of Los Angeles, California, and SAb Biotherapeutics, Inc. of Sioux Falls, South Dakota. The products in development include convalescent plasma and hyperimmune globulin; both are based on the blood plasma of people who have recovered from a disease. Convalescent plasma contains antibodies produced by the immune system to fight bacteria or viruses.

Development of a Rapid Diagnostic Test: BARDA and Vela Diagnostics USA, Inc. are entering into a partnership to [develop a rapid diagnostic test](#) for use on two instrument platforms

to aid in the detection of COVID-19 infections. Diagnostics on multiple platforms are needed to test as many people as possible and identify those who are infected in order to slow the pandemic. The company will develop two tests both of which would allow rapid analysis and early detection of SARS-CoV-2 in upper respiratory tract specimens from symptomatic individuals for effective patient management. Upon successful development, the company will seek Emergency Use Authorizations (EUAs) from the FDA for both the manual and automated tests.

Call for Plasma Donations among Recovered COVID Patients: FDA released information calling for [plasma donations among recovered COVID patients](#). If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma. Because you fought the infection, your plasma now contains COVID-19 antibodies. These antibodies provided one way for your immune system to fight the virus when you were sick, so your plasma may be able to be used to help others fight off the disease. The information includes information about convalescent plasma, eligibility standards and how to donate.

Information about Hand Sanitizers: FDA updated their [FAQ on Hand Sanitizers](#), reminding everyone that the best way to prevent the spread of infections and decrease the risk of getting sick is by washing your hands with plain soap and water, but if soap and water are not available, CDC recommends consumers use an alcohol-based hand sanitizer that contains at least 60% alcohol. The FAQs also cover information about hand sanitizer, its effectiveness against COVID-19, what to do if a child ingests hand sanitizer and additional resources on the topic.

Product Specific Guidance for Chloroquine Phosphate and Hydroxychloroquine Sulfate: In anticipation of increased demand for chloroquine phosphate and hydroxychloroquine sulfate, the FDA is taking [steps to ensure that adequate supply of these drug products is available](#) by publishing product-specific guidances (PSGs) to support generic drug development for these drugs. The new PSG for chloroquine phosphate clarifies that the product is AA rated in the Approved Drug Products with Therapeutic Equivalence Evaluations publication (Orange Book), meaning that there are no known or suspected bioequivalence problems, and no in vivo studies are necessary. The revised PSG for hydroxychloroquine sulfate adds advice about a Biopharmaceutics Classification System-based biowaiver option. The FDA is currently prioritizing review of any newly submitted Abbreviated New Drug Applications (ANDAs) for chloroquine phosphate and hydroxychloroquine sulfate under [MAPP 5240.3: Prioritization of the Review of Original ANDAs, Amendments, and Supplements](#).

Information on Blood Glucose Meters While in the Hospital: The FDA posted [FAQs on home-use blood glucose meters](#) recognizing that home-use blood glucose meters may be used by patients with diabetes who are hospitalized due to COVID-19 to check their own blood glucose levels and provide the readings to the health care personnel caring for them. As part of efforts to help protect health care providers and patients from exposure to COVID-19 to the extent possible during this pandemic, this page provides answers to frequently asked questions that health care providers and other personnel at health care settings may have on patients' use of these devices.

Expanding Availability of Digital Health Therapeutic Devices: FDA issued guidance to provide a [policy to help expand the availability of digital health therapeutic devices for psychiatric disorders](#) to facilitate consumer and patient use while reducing user and healthcare provider contact and potential exposure to COVID-19 during this pandemic.

Information for Specific Populations

Updated Information on Infection Prevention and Control in Healthcare Settings: CDC published revised [Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 \(COVID-19\) in Healthcare Settings](#). The information includes: recommending screening everyone for fever/symptoms before entering a healthcare facility; aligning with community masking guidance to address source control and asymptomatic/pre-symptomatic transmission; emphasizing that cloth face coverings are not considered PPE; medical facemasks, if available, should be reserved for healthcare personnel (HCP); focusing on universal masking and symptom screening for HCP instead of retrospective risk assessment and contact tracing; and considering dedicating space to care for COVID-19 positive residents (cohort units) in nursing home.

Updated Clinical Guidance for Public Health Personnel Evaluating Patients: CDC updated their interim guidance for [Public Health Personnel Evaluating Persons Under Investigation \(PUIs\) and Asymptomatic Close Contacts of Confirmed Cases at their Home](#). The updates reflect the latest information on PPE recommendations, updated language on collection of diagnostic respiratory specimens related to aerosol- vs. non-aerosol generating activities, and updated recommendations to include placing a facemask on symptomatic patients as source control.

Information on Transfers from Long-Term Care Facilities: CMS is providing [supplemental information for transferring or discharging residents between skilled nursing facilities and/or nursing facilities based on COVID-19 status](#) (i.e., positive, negative, unknown/under observation). In general, if two or more certified long-term care facilities want to transfer or discharge residents between themselves for the purposes of cohorting, they do not need any additional approval to do so. However, if a certified long-term care facility would like to transfer or discharge residents to a non-certified location for the purposes of cohorting, they need approval from the State Survey Agency.

Postponement of Risk Adjustment Data Validation: To facilitate the nation's response to COVID-19, CMS is announcing the [postponement of the 2019 benefit year HHS Risk Adjustment Data Validation \(HHS-RADV\) process](#). This action will allow individual and small group health insurance issuers and providers to focus on the health and safety threats currently faced by enrollees, participants, and other impacted individuals due to the COVID-19 pandemic. CMS intends to provide future guidance in the summer of 2020 on the updated timeline for 2019 benefit year HHS-RADV activities that are planned to begin in 2021. CMS previously announced a similar suspension of the Medicare Advantage RADV program.

Updated Medicaid and CHIP Information on Enhanced Federal Funding: CMS released additional [Medicaid and CHIP guidance to states](#) on the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security (CARES). The Frequently Asked

Questions (FAQs) address enhanced federal Medicaid funding and other topics during the COVID-19 national emergency. The guidance covers topics such as: The Emergency Period described in the Families First Coronavirus Response Act; The New Optional Medicaid Eligibility Group; Benefits and Cost sharing for COVID-related testing and diagnostic services; Implications for the Children’s Health Insurance Program; Implications for the Basic Health Program; Additional Questions on the Increased FMAP under Section 6008 of the FFCRA; Availability of 100 percent FMAP and Other Financial Questions; and Coronavirus Aid, Relief, and Economic Security (CARES) Act.

Precautions to Take if You are Sick: CDC updated their information on [What to Do If You are Sick](#). The information includes multiple steps to take as well as additional resources and translations in multiple language.

Recommendations on Cleaning and Disinfecting Facilities: CDC released information with recommendations on [Cleaning and Disinfecting Your Facility](#). The information includes everyday steps, steps to take when someone is sick, and considerations for employers.

Funding to Support Child Care and Development Block Grant: ACF released [\\$3.5 billion to support the Child Care and Development Block Grant](#). This funding will support states, territories, and tribes to provide assistance to child care providers in order to financially support them during the public health crisis. This additional funding can also help support healthcare workers, first responders, and other essential workers playing critical roles during this crisis. Funds will be released to state, territory, and tribal Child Care and Development Fund programs. Additional information about the Child Care and Development Block Grant specific to this public health crisis can be found on the Office of Child Care website: <https://www.acf.hhs.gov/occ/resource/occ-covid-19-resources>.

Research Updates

Effects of Community Mitigation: CDC published a MMWR weekly report on [Timing of Community Mitigation and Changes in Reported COVID-19 and Community Mobility — Four U.S. Metropolitan Areas, February 26–April 1, 2020](#). Implementing community mitigation strategies, including personal protective measures persons should adopt in community settings, social distancing, and environmental cleaning in community settings, during a pandemic can slow the spread of infections. During February 26–April 1, 2020, community mobility (a proxy measure for social distancing) in the metropolitan areas of Seattle, San Francisco, New York City, and New Orleans declined, decreasing with each community mitigation policy issued and as case counts increased. Public policies to increase compliance with community mitigation strategies might be effective in decreasing community mobility; however, more information is needed to assess impact on disease transmission.

Characteristics of Healthcare Personnel with COVID-19: CDC published a new report in the MMWR on [Characteristics of Health Care Personnel with COVID-19 — United States, February 12–April 9, 2020](#). Prior to this report, limited information was available about COVID-19 infections among U.S. health care personnel (HCP). The report found that: of 9,282 U.S. COVID-19 cases reported among HCP, median age was 42 years, and 73% were female,

reflecting these distributions among the HCP workforce. HCP patients reported contact with COVID-19 patients in health care, household, and community settings. Most HCP patients were not hospitalized; however, severe outcomes, including death, were reported among all age groups. Going forward, it is critical to ensure the health and safety of HCP, both at work and in the community. Improving surveillance through routine reporting of occupation and industry not only benefits HCP, but all workers during the COVID-19 pandemic.

Findings on Transmission of COVID-19 to Health Care Personnel: CDC published a new report in the MMWR on [Transmission of COVID-19 to Healthcare Personnel during Exposures to a Hospitalized Patient — Solano County, California, February 2020](#). Health care personnel (HCP) are at heightened risk of acquiring COVID-19 infection, but limited information exists about transmission in health care settings. This report found that among 121 HCP exposed to a patient with unrecognized COVID-19, 43 became symptomatic and were tested for SARS-CoV-2, of whom three had positive test results; all three had unprotected patient contact. Exposures while performing physical examinations or during nebulizer treatments were more common among HCP with COVID-19. Unprotected, prolonged patient contact, as well as certain exposures, including some aerosol-generating procedures, were associated with SARS-CoV-2 infection in HCP. Going forward, early recognition and isolation of patients with possible infection and recommended PPE use can help minimize unprotected, high-risk HCP exposures and protect the health care workforce.