

HHS COVID-19 April 2, 2020 Update

The big update today is that **CDC will be issuing recommendations for people to wear a non-medical mask upon leaving home to conduct essential business.** We will continue to prioritize medical masks for healthcare workers, but are recommending individuals wear a basic cloth or fabric mask that can be washed or reused. Recent studies are showing that the virus can be passed along even when a person is asymptomatic and so wearing a mask will help prevent you from infecting others.

Optimizing the Supply of PPE: CDC updated their [guidance on strategies to optimize the supply of PPE](#). This document contains information for each different type of PPE and specific ways to extend the capacity and supply of PPE. Relatedly, CDC has updated their guidance and graphics on the [Use of Personal Protective Equipment when Caring for Individuals with Suspected or Confirmed COVID-19](#). The updated information shows how to appropriately don and doff PPE with graphics showing both how to wear an N-95 respirator as well as a facemask as an acceptable alternative.

A Warning to Fraudulent Companies and Price Gougers: As the President has repeatedly warned, there will be no tolerance for those trying to exploit this pandemic through fraud or price-gouging. Yesterday we reported on FDA's action against companies making specious claims about COVID-19 cure-alls, with another [warning letter](#) sent out to Neuro XPF, a company selling CBD with claims that it can treat and cure COVID-19. Today [HHS and DOJ confiscated over 500,000 items of medical supplies that were being hoarded](#). The recovered supplies were promptly distributed to New York and New Jersey and included 192,000 N95 respirators, 598,000 medical grade gloves and 130,000 surgical masks, procedure masks, N100 masks, surgical gowns, disinfectant towels, particulate filters, bottles of hand sanitizer, and bottles of spray disinfectant. The supplies were obtained as part of The Defense Production Act and Presidential Executive Order that prevents the accumulation of medical supplies critical to the COVID-19 response in excess of reasonable demands of business, personal, or home consumption, or for the purpose of resale at prices in excess of prevailing market prices. As a reminder, if you would like to sell medical supplies to the Government, you should contact FEMA at <https://www.fema.gov/coronavirus/how-to-help>.

Increased Flexibility Around HIPAA: The Office of Civil Rights announced that it will exercise its enforcement discretion and will [not impose penalties for violations of certain provisions of the HIPAA Privacy Rule](#) against health care providers or their business associates for the good faith uses and disclosures of protected health information (PHI) by business associates for public health and health oversight activities during the COVID-19 nationwide

public health emergency. This rule will allow for more freedom to cooperate and exchange information with public health and oversight agencies to better assist patients.

A Call to Donate Blood and an Expansion of the Population Who is Eligible to Donate: The COVID-19 pandemic has caused unprecedented challenges to the U.S. blood supply. People who donate blood are part of our critical infrastructure industries. More donations are needed at this time and we hope people will continue to take the time to donate blood. Based on recently completed studies and epidemiologic data, the FDA has concluded that [current policies regarding certain donor eligibility criteria can be modified](#) without compromising the safety of the blood supply. New recommendations have been released regarding donations and populations that can donate to reducing risk of HIV transmission, transfusion-transmitted malaria, and Creutzfeldt-Jacobs disease.

Now Up to 23 EUAs on Diagnostic Tests: During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 23 [emergency use authorizations](#) have been issued for diagnostic tests. On March 31st FDA [issued an EUA](#) that authorizes eligible molecular-based laboratory developed tests, or LDTs, that are developed and used by a single CLIA high complexity laboratory. Under this EUA, FDA has authorized Yale New Haven Hospital's SARS-CoV-2 PCR test. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its [COVID-19 Diagnostics FAQ](#) up to date.

Preparedness and Planning Guidance for Childcare Centers that Remain Open: No matter the level of transmission in a community, every child care program should have a plan in place to protect staff, children, and their families from the spread of COVID-19. This document is meant to help administrators create emergency operations plans and tailor them to your community's level of transmission. The [guidance](#) includes recommendations for social distancing, cleaning and disinfecting, sanitization of toys, and how to address drop-off and pick-up.

Telehealth for Medicaid Substance Use Disorder Services: CMS released an [Informational Bulletin](#) to states that identifies opportunities for telehealth delivery methods to increase access to Medicaid services and federal reimbursement for services and treatment for substance use disorders under Medicaid using services delivered via telehealth, including in school-based health centers. This Informational Bulletin is composed of two parts: Rural Health Care and Medicaid Telehealth Flexibilities; and Medicaid Substance Use Disorder Treatment via Telehealth. While this guidance applies to states generally, it includes information useful for states in light of the ongoing response to the COVID-19 virus. Maximizing telehealth flexibilities will help prevent vulnerable beneficiaries from unnecessarily entering a healthcare facility when their needs can be met remotely.

Updated FAQs for Health Centers: HRSA recently updated their [COVID-19 FAQs](#) with additional questions to address the Federal Tort Claims Act among other flexibilities that have been enacted with respect to HRSA grantees and programs.

Guidance and Research on Reusing Respirators in Crisis Situations: Disposable filtering facepiece respirators (FFRs) are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs. This document summarizes research about decontamination of FFRs before reuse. The [Decontamination and Reuse of Filtering Facepiece Respirators](#) document includes recommendations for decontamination in crisis situations and a summary of the effects on performance based on the decontamination method.

The Importance of Fit Testing Respirators: NIOSH released a blog posting on [Fit Testing for Respirators](#) and alterations to the standard process that can be made during an infectious disease outbreak to more quickly train and fit test healthcare workers.

Availability of Reference Grade Sequence Data for SARS-CoV-2: The FDA, CDC, BARDA, the Institute for Genome Sciences at the University of Maryland and the National Center for Biotechnology Information (NCBI), developed quality-controlled, [reference sequence data for the SARS-CoV-2 reference strain](#) for the United States. Availability of traceable and quality-controlled data will help test developers and vaccine developers to expedite development of medical countermeasures, identify new or more stable targets for future tests, enable in silico confirmation of targets, support development of synthetic reference material, and enable viral population/quasi species analysis.

Helpful Resources: This is a time of great uncertainty. For mental health concerns, we want to remind everyone of the SAMHSA disaster distress line, which can be accessed via 800-985-5990; by texting “talkwithus” to 66746 or visiting [disasterdistress.samhsa.gov](#). ASPR also developed a [COVID-19 resource page](#) that provides easy access to the plans, tools and practices that have been developed. Lastly, a new website was also established that outlines the paycheck protection program and other programs and resources available from the Small Business Administration at [coronavirus.gov/smallbusiness](#).