

HHS COVID-19 Update – May 28, 2020

Funding

\$15 Million for Rural Tribal Communities: HRSA awarded \$15 million to 52 Tribes, Tribal organizations, urban Indian health organizations, and other health services providers to Tribes across 20 states to prepare, prevent, and respond to COVID-19 in rural tribal communities. HRSA made awards to Federally Recognized Tribes and other tribal organizations based on their needs and capacity to implement COVID-19 related activities in their rural communities. Tribes could request up to \$300K in funding for these activities through the Rural Tribal COVID-19 Response (RTCR) program. For the complete list of Rural Tribal COVID-19 Response program award recipients, visit: www.hrsa.gov/rural-health/coronavirus/rural-tribal-covid-19-response-fy20-awards.

Testing and Treatment

Ensuring Accuracy of COVID-19 Tests: FDA took a new step to support the agency's [evaluation of diagnostic tests for COVID-19](#), by providing a SARS-CoV-2 reference panel. Reference panels are an additional step to ensure the quality of the tests, validation of new assays, test calibration, and monitoring of assay performance. These types of reference panels have proven to be an invaluable resource in the development of accurate, reliable, and validated diagnostic tests for detecting infectious diseases.

Assisting with Earlier Identification of Respiratory Failure: Yesterday, the FDA issued an [Emergency Use Authorization \(EUA\)](#) for emergency use of the CLEWICU System of CLEW Medical Ltd for use by healthcare providers in the intensive care unit (ICU) as a diagnostic aid to assist with the early identification of adult patients who are likely to be diagnosed with respiratory failure or hemodynamic instability which are common complications associated with COVID-19. The CLEWICU system utilizes the full range of available patient data to provide continuous predictions based on data driven algorithms and machine learning models. The CLEWICU system delivers workflow improvements and dynamic worklist prioritization, enabling healthcare providers to spend less time on administration and more time on patient treatment. In this way, CLEWICU may reduce the contact between ICU personnel and patients by providing the ICU clinician the ability to view the patient risk status from a remote location.

Billing CMS for Medicare Fee-for-Service: CMS updated their [COVID-19 FAQ on Medicare Fee-for-Service](#). The FAQs cover all topics including billing for testing, treatment, and different types of settings. A few answers in this document explain provisions from the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law No. 116-136 (March 27, 2020). CMS

is thoroughly assessing this new legislation and new and revised FAQs will be released as implementation plans are announced.

Disinfecting Your Home if Someone is Sick: CDC updated their information on [Disinfecting your home if someone is sick](#). The information includes how to clean and disinfect your home based on surface type and additional actions to take if someone in your household is sick.

Triaging Patients in Non-US Healthcare Settings: CDC updated their information on [Standard Operating Procedure \(SOP\) for Triage of Suspected COVID-19 Patients in non-US Healthcare Settings: Early Identification and Prevention of Transmission during Triage](#). The updated include Edits to clarify how healthcare workers can protect themselves during triage and updates to triage algorithm to allow for fever (>38°C) OR history of fever.

Information on Formal Meetings and User Fee Applications: The FDA issued a guidance document entitled “[Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications](#)” to provide answers to frequently asked questions. The agency is providing answers concerning certain aspects of sponsor requests for formal meetings with industry, user fee applications goals and timelines, and prioritization of drug and biological application reviews during the public health emergency.

Warning to Fraudulent Actors: The FDA and Federal Trade Commission (FTC) issued warning letters to four companies for promoting and participating in the sale of fraudulent COVID-19 products, as part of the agency’s effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider. The companies include: [CBD Gaze](#), [Alternavita](#), [Musthavemom.com](#), and [Careful Cents, LLC](#). A judge in the U.S. District Court for the Eastern District of Oklahoma entered a preliminary injunction against Xephyr LLC, doing business as N-Ergetics.

Testing Updates: During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus. To date, the FDA has authorized 113 tests under EUAs, which include 100 molecular tests, 12 antibody tests, and 1 antigen test.

PPE

Enforcing Face Masks and Respirators: FDA updated information on their [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency \(Revised\)](#). FDA is issuing this guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for healthcare personnel (HCP)¹ for the duration of the COVID-19 public health emergency.

Decontaminating PPE: FDA released guidance on [Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#). FDA is issuing this guidance to provide recommendations for sponsors of decontamination and bioburden reduction systems about what information should be included in a pre-Emergency Use Authorization (pre-EUA) and/or EUA request to help facilitate FDA's efficient review of such request. This guidance provides these recommendations based on the device's intended use with respect to the level (tier) of decontamination or bioburden reduction, based on the sponsor's available data.

Sterilization and Decontamination of N95 Respirators: The FDA issued a [letter to health care providers](#) to remind reprocessing staff in health care facilities to use the correct sterilization cycle associated with certain models of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and to only decontaminate compatible N95 or N95-equivalent respirators for reuse during the COVID-19 pandemic. These sterilization systems help increase the availability of respirators by allowing decontaminated compatible respirators to be reused so health care workers on the front lines can be better protected when providing care to patients with COVID-19.

Addressing Potential Shortages of PPE: Yesterday, the FDA issued two guidance documents (one new guidance and one revised guidance) for industry to help address potential shortages of face masks, surgical masks, respirators, and face shields for use during the COVID-19 public health emergency: [Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#) and [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency \(Revised\)](#). These guidances help to address potential shortages by facilitating the safe reuse and conservation of surgical masks and respirators for medical purposes through the use of decontamination and bioburden reduction systems and providing recommendations of alternatives and updated options for when FDA-cleared or NIOSH-approved N95 respirators are not available.

Information for Specific Populations

Letter on Encouraging Family Support: ACF and HRSA released a joint letter on [encouraging family support](#). The intent of this letter is to encourage family support, maternal and child health, and early childhood programs (including Head Start, home visiting, early intervention, and other early care and learning programs) to promote family strengthening and prevention strategies via virtual, electronic, telephonic, or other safe means during the COVID-19 pandemic.

Guidance for Pharmacists: CDC updated their [Guidance for Pharmacists and Pharmacy Technicians](#) in Community Pharmacies during the COVID-19 Response. The updates include information on providing clinical services according to the [Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic](#), which includes

considerations for delivering non-COVID-19 care by the degree of community transmission and potential for patient harm if care is deferred.

Guidance for General Population Shelters: CDC updated their [Guidance for General Population Shelters](#). This document is intended for use by federal, state, local, and tribal jurisdictions in the United States. It should be used in conjunction with existing shelter operation and management plans, procedures, guidance, resources, and systems, and is not a substitute for shelter planning and preparedness activities. Purpose This document provides interim guidance to reduce the risk of introducing and transmitting COVID-19 in general population disaster shelters before, during, or after a disaster. This document should not be applied to medical support shelters or functional needs shelters.

Guidance for Providers Serving People with Developmental and Behavioral Disorders: CDC updated their [Guidance for Direct Service Providers, Caregivers, Parents, and People with Developmental and Behavioral Disorders](#). People with developmental and behavioral disorders may live in group homes or interact with Direct Service Providers (DSPs). CDC has provided guidance for [group homes](#) and [DSPs](#) who provide assistance to people with disabilities. Many of the recommendations for COVID-19 preparation and response described in those guidance documents also apply to caregivers and DSPs for people with developmental and behavioral disorders.

Guidance for Individuals with Disabilities Living in Group Homes: CDC updated their [Guidance for Group Homes for Individuals with Disabilities](#). Group homes (GHs) for people with disabilities can vary in size from small to larger congregate settings. In congregate living settings, several factors may facilitate the introduction and spread of SARS-CoV-2, the virus that causes COVID-19. Some of these factors include residents employed outside the home, residents who require close contact with staff or Direct Service Providers, residents who have trouble understanding information or practicing preventive measures, and residents in shared living spaces. In addition, GH residents who have underlying medical conditions may be at risk of serious illness with COVID-19.

Screening at Homeless Shelters: CDC released information on [Screening Clients for COVID-19 at Homeless Shelters or Encampments](#). The following is a screening tool that can be used to identify people with possible symptoms of coronavirus disease 2019 (COVID-19). Although not every person who has symptoms will have COVID-19, conducting daily screenings consisting of a series of simple questions can help identify people who may need medical care or isolation.

Information for Sanitation and Wastewater Workers: CDC updated their [Information for Sanitation and Wastewater Workers on COVID-19](#). Recently, the virus that causes COVID-19 has been found in untreated wastewater. While data are limited, there is no information to date that anyone has become sick with COVID-19 because of exposure to wastewater. Standard practices associated with wastewater treatment plant operations should be sufficient to protect wastewater workers from the virus that causes COVID-19. These standard practices can include engineering and administrative controls, hygiene precautions, specific safe work practices, and personal protective equipment (PPE) normally required when handling untreated wastewater.

Reporting Closures of Food Establishments: The FDA issued a guidance entitled “[Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID-19 Public Health Emergency.](#)” The guidance provides a mechanism for FDA-regulated establishments (human food facilities and farms) to voluntarily notify the agency of temporary closures and significant reductions in operations and to request assistance from FDA on issues that might affect continuity of their operations during the pandemic.

Research Findings

Updated Death Forecasts: CDC updated their [COVID-19 Forecasts: Cumulative Deaths](#). This week CDC received 15 individual national forecasts. This week’s national ensemble forecast indicates that the rate of increase in cumulative COVID-19 deaths is continuing to decline.

Updated Hospitalization Forecasts: CDC updated their [Interpretation of Forecasts of New Hospitalizations](#). Forecasts that estimate the numbers of daily new COVID-19 hospitalizations over the next four weeks vary considerably. The two national forecasts included here—from Columbia University and the Georgia Institute of Technology—predict different rates of hospitalizations over time, with large uncertainty bounds. Standardized reporting of state-level hospitalization data is limited, so most forecasts estimate the number of new hospitalizations from data sets of COVID-19 cases or deaths. The use of different data sets, with different limitations—along with the use of different assumptions about social distancing—results in high variation between forecasts.

Nominations for National Advisory Committee on Children and Disasters: ASPR announces establishment of the National Advisory Committee on Children and Disasters (NACCD). [See the notice published in the Federal Register](#). The Advisory Committee will provide advice and consultation to the HHS Secretary on pediatric medical disaster planning, preparedness, response, and recovery with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response (ASPR) will provide management and administrative oversight to support the activities of the Advisory Committee. The Office of the Secretary is accepting application submissions from qualified individuals who wish to be considered for membership on the NACCD. Up to 13 new voting members with expertise in pediatric medical disaster planning, preparedness, response, or recovery will be selected for the Committee. Application period closes June 20, 2020.