

HHS COVID-19 Update – May 12, 2020

Testing

Testing Support to States: The White House released information yesterday on [providing test resources to states](#). In addition, today, the Administration posted information on [how much funding and how many swabs each state](#) will receive as part of the effort to bolster testing capacity.

Updates on Handling Specimens: CDC updated their information on [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with COVID-19](#). The updates include new recommendations on point-of-care testing guidance for COVID-19.

Updates on Testing Policy: The FDA updated the [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#). FDA is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. The update includes EUA submission templates for molecular, antigen, and serology tests. Developers may choose to use these templates to facilitate the preparation, submission, and authorization of an EUA for various types of COVID-19 tests.

Diagnostics Update: During the COVID-19 pandemic, the FDA has worked with more than 385 test developers who have said they will be submitting EUA requests to the FDA for tests that detect the virus. To date, the FDA has issued 92 EUAs, which includes 12 antibody tests and 1 antigen test. The FDA has been notified that more than 245 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.

Treatment

Accelerating Development of Prevention and Treatment Options: FDA released information on [new actions to accelerate the development of novel prevention, treatment options for COVID-19](#). FDA is providing new guidance with recommendations for innovators and researchers conducting work in this area. These guidance documents aim to make the process for submitting applications to initiate studies for new drugs and biological products more efficient and outline recommendations for ways to design clinical trials to evaluate safety and effectiveness of these medical products for COVID-19.

Coding for COVID-19: CDC released information on the [ICD-10-CM Official Coding and Reporting Guidelines, April 1, 2020 through September 30, 2020](#). The document includes coding guidelines for all types of COVID-19 diagnoses.

Ensuring Access to Sedation while Under Mechanical Ventilation: The virus that causes COVID-19 has led to an increased number of people with severe respiratory illness. As a result, there is a shortage of FDA-approved drugs such as propofol that are used for sedation of mechanically ventilated patients. The FDA issued an [Emergency Use Authorization \(EUA\)](#) for [emergency use of the Fresenius Propoven 2% Emulsion](#) to maintain sedation via continuous infusion in patients older than 16 who require mechanical ventilation in an ICU during the COVID-19 public health emergency. Fresenius Propoven 2% Emulsion has important differences in its formulation compared to FDA-approved propofol drugs; providers should consult the [Health Care Provider Fact Sheet](#) for more information before administering it.

Additional Information on Conducting Clinical Trials: The FDA added content to the question-and-answer appendix in its guidance titled [Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#). The updated guidance includes new content with considerations for using alternate laboratories or imaging centers, holding trial participant visits via video conference, and conducting required postmarketing clinical trials. The guidance also includes updated information about managing protocol deviations and amendments to ongoing trials, and about consulting with the FDA regarding administering investigational product infusions at home rather than at the clinical trial site.

New Drug Applications Approved: The FDA approved two Abbreviated New Drug Applications relevant to COVID-19, and both medicines are listed in the FDA Drug Shortage Database. FDA recognizes the increased demand for certain products during the novel coronavirus pandemic and we remain deeply committed to facilitating access to medical products to help address critical needs of the American public. [Cisatracurium besylate injection USP 20 mg/10 mL](#) is indicated to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Side effects of cisatracurium include bradycardia, hypotension, flushing, bronchospasm, and rash. [Azithromycin Tablets USP, 600 mg](#), is indicated for mild to moderate infections caused by designated, susceptible bacteria that cause certain sexually transmitted diseases and mycobacterial infections. Side effects of azithromycin tablets include hypersensitivity, QT prolongation, diarrhea, nausea, abdominal pain, and vomiting.

Recommendations for Postmarketing Adverse Event Reporting: FDA released information on [Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic](#). This guidance provides recommendations to industry regarding postmarketing adverse event reporting for drugs, biologics, medical devices, combination products, and dietary supplements during a pandemic. FDA anticipates that during a pandemic, industry and FDA workforces may be reduced because of high employee absenteeism while reporting of adverse events related to widespread use of medical products indicated for the treatment or prevention of the pathogen causing the pandemic may increase. The extent of these possible changes is unknown. This guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for medical products and dietary supplements during a pandemic.

Reopening America

Updates on Surveillance Inspections: FDA released information with [updates on surveillance inspections during COVID-19](#). During COVID-19, the U.S. Food and Drug Administration will continue to utilize and implement additional alternative inspection tools and approaches while postponing domestic and foreign routine surveillance inspections. This will continue as local, national and international conditions warrant, with the exception of certain mission critical inspections. Mission critical inspections are identified on a case-by-case basis and conducted with appropriate safety measures in place. The FDA is collaborating with the CDC to develop a process that would govern how and where to return to on-site facility surveillance inspections in accordance with the gating criteria outlined in the [White House Guidelines for Opening Up America Again](#). We expect this to be a phased approach driven by scientific data. Our priority and commitment are to first protect the health and well-being of not only our own highly skilled workforce and state contract inspectors, but also the health of workers in the important industries we regulate.

Guidance for Water Parks: CDC released information on [Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19](#). As public aquatic venues open in some areas, CDC offers considerations for the safety of those who operate, manage, and use public pools, hot tubs, and water playgrounds. The considerations include promoting behaviors that prevent the spread of COVID-19, maintaining healthy environments, maintaining healthy operations, and preparing for when someone gets sick.

PPE

Face Mask Information: FDA released information on [Face Masks and Surgical Masks for COVID-19: Manufacturing, Purchasing, Importing, and Donating Masks During the Public Health Emergency](#). In general, masks are used by the general public and health care personnel to prevent the spread of infection or illness. This page is for people and organizations who are new to working with the FDA. To help expand the availability of face masks and surgical masks, the FDA is providing regulatory flexibility, as described in our policy for face masks and surgical masks that is in effect during the COVID-19 pandemic. The information also includes FAQs on different types of masks, process for manufacturing, importing, purchasing, and donating.

Purchasing Respirators from Another Country: CDC updated their guidance on [Factors to Consider When Planning to Purchase Respirators from Another Country](#). Key factors to consider include evaluation of the device, evaluation of the manufacturer or seller, evaluation of the contract terms, and FDA guidance on Emergency Use Authorization.

Information for Specific Populations

Information for Pediatric Providers: CDC updated [Information for Pediatric Healthcare Providers](#). This information informs pediatric healthcare providers of information available on children with COVID-19 and can be used when managing pediatric patients with confirmed or suspected COVID-19.

Information on Worker Safety and Supports: CDC created a new webpage for each industry sector on [Worker Safety and Support](#). The webpage includes information on planning, preparing

and responding to COVID-19 and has specific information on coping and resilience, workplace guidance, and safety steps for specific populations.

Tips for Staying Safe While Running Errands: CDC updated their information on [Running Essential Errands](#). The information includes tips and advice for what to do when grocery shopping, picking up take-out, banking, getting gas, and doctor visits.

People with Hemoglobin Disorders at Higher Risk: CDC updated their webpage on [Groups at Higher Risk for Severe Illness](#). The risk group added includes people with hemoglobin disorders such as sickle cell disease (SCD) and thalassemia. Living with a hemoglobin disorder can lead to serious multi-organ complications, and underlying medical conditions (such as heart disease, liver disease, diabetes, iron overload, kidney disease, viral infections, or weakened immune system) may increase the risk of severe illness from COVID-19.

Information for Title VI Grantees: ACL updated information in their [COVID FAQs for Title VI Grantees](#). Updated information includes new details on allowable uses for the funds, information on caregiver services, disaster operations, and helpful links.

Impact of COVID-19 on Black and Latino Communities: SAMHSA released a document on [Double Jeopardy: COVID-19 and Behavioral Health Disparities for Black and Latino Communities in the U.S.](#) The coronavirus (COVID-19) pandemic has revealed deep-seated inequities in health care for communities of color and amplifies social and economic factors that contribute to poor health outcomes. Recent news reports indicate that the pandemic disproportionately impacts communities of color, compounding longstanding racial disparities.

Information for Law Enforcement on Naloxone: SAMHSA released [Guidance for Law Enforcement and First Responders Administering Naloxone](#). It is essential that naloxone continue to be administered during this time period. SAMHSA recognizes the concerns about COVID-19 exposure and recommends intranasal naloxone administration to promote first responder safety; if law enforcement or first responders feel the use of intranasal naloxone poses too great a risk, intramuscular naloxone may be used.

Information on Unsheltered Homelessness: CDC updated information on [interim guidance on unsheltered homelessness and Coronavirus Disease 2019 \(COVID-19\) for homeless service providers and local officials](#). Updates include description of “whole community” approach; clarification of outreach staff guidance; and clarification of encampment guidance.