

HHS COVID-19 April 29, 2020 Update

Promising Early Results from Remdesivir Trial: The [NIH announced](#) that hospitalized patients with advanced COVID-19 and lung involvement who received Remdesivir—an investigational broad-spectrum antiviral treatment administered via daily infusion—recovered, on average, faster than similar patients who received placebo, according to a preliminary data analysis from a randomized, controlled trial involving 1063 patients. Secretary Azar noted “Through the efforts of NIH, FDA, and other parts of HHS, the Trump Administration has been working relentlessly to get promising treatments like Remdesivir to the frontlines and save lives.”

Reopening America

Reopening Cleaning Guidance: CDC has released reopening guidance for [Cleaning and Disinfecting Public Spaces, Workplaces, Businesses, Schools, and Homes](#). This guidance is intended for all Americans, whether you own a business, run a school, or want to ensure the cleanliness and safety of your home. This document provides a general framework for cleaning and disinfection practices. Cleaning and disinfecting public spaces including your workplace, school, home, and business will require you to: develop your plan; implement your plan; and maintain and revise your plan.

Testing and Treatment

Rapid Testing Development Competition: NIH has released information about their [Rapid Acceleration of Diagnostics \(RADx\) program](#). RADx aim is to speed the development and commercialization of tests that can rapidly “see” if people have been infected with SARS-CoV-2 with very high sensitivity and specificity, meaning there would be few false negatives and false positives. A key part of this effort, will be a national technology development competition that’s open to all comers. In this competition, which begins a bit like a “shark tank,” participants will vie for an ultimate share of an approximately \$500 million fund that will be awarded to help advance the most-promising testing technologies.

Contact Tracing Guidance and Resources: CDC released their [principles and information on contact tracing](#) which highlights the basic principles of contact tracing to stop COVID-19 transmission, includes detailed guidance for health departments and potential contact tracers information is forthcoming. CDC also updated the information on their [contact tracing](#) resource page to include new resources and key concepts on contact tracing. CDC guidance for COVID-19 may be adapted by state and local health departments to respond to rapidly changing local circumstances.

Serology Surveillance Strategy: CDC is working with state, local, territorial, academic, and commercial partners to better understand COVID-19 in the United States. CDC’s [serology surveillance strategy](#) includes using serology testing for surveillance to better understand how many infections with SARS-CoV-2 have occurred at different points in time, in different locations, and within different populations in the United States.

Testing Clinical Specimens: CDC released updated information on [Testing Clinical Specimens from Persons with COVID-19](#). Updates include new information on viral transport medium (VTM) to note that some point-of-care tests advise against its use and alignment of the guidance on swab types with FDA guidance.

Ask for Contributions to Scientific Research: CMS released a [letter to clinicians participating in the Merit-based Incentive Payment System](#). CMS is encouraging the many clinicians, including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and others, who participate in the Quality Payment Program (QPP) to contribute to scientific research and evidence through clinical trials to help fight the COVID-19 pandemic. Clinicians who participate in a clinical trial and report their findings to a clinical data repository or registry may now earn credit in the Merit-based Incentive Payment System (MIPS) for the 2020 Performance Period by attesting to the new COVID-19 Clinical Trials improvement activity.

Video to Explain FDA Emergency Use Authorizations: FDA issued a new [video resource](#) explaining Emergency Use Authorizations (EUAs), one of several tools FDA uses to help make important medical products available quickly during public health emergencies like the COVID-19 pandemic. Generally, EUAs provide more timely access to drugs, diagnostic tests and/or other critical medical products that can help diagnose, treat and/or prevent COVID-19. When deciding whether to issue an EUA, the FDA evaluates the available scientific evidence very quickly and carefully balances any known and potential benefits and/or risks of these products to the public.

Warning to Fraudulent Actors: The FDA and Federal Trade Commission (FTC) issued warning letters to two companies for selling 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 first seller warned, [Hopewell Essential Oils](#), offers essential oils and herbal products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19. The second seller warned, [Santiste Labs LLC](#), the “Defend™ Patch,” a transdermal patch containing a “composition of botanical oils,” for sale in the U.S. with misleading claims that the product is safe and/or effective for the prevention or treatment of COVID-19.

Diagnostics Update: During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, the FDA has issued 50 individual [emergency use authorizations](#) for test kit manufacturers and laboratories. In addition, 22

authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs). The FDA has been notified that more than 230 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.

Information for Manufacturers of Generic Drugs: The FDA posted [information and resources](#) to assist manufacturers submitting generic drug applications with bioequivalence studies that may be impacted during COVID-19.

Supplies

Ensuring Food Supply Safety: Last night, President Trump [announced that he was invoking the Defense Production Act to ensure that Americans have a reliable supply of products like beef, pork, and poultry](#). Under the order, the Department of Agriculture is directed to ensure America's meat and poultry processors continue operations uninterrupted to the maximum extent possible. To ensure worker safety, these processors will continue to follow the latest guidelines from the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA). This action will further ensure that vitally important food processors are able to continue to operate safely and meet the consumer needs of the American people.

Mask, Gown and Glove Conservation Strategies: FDA released an updated [letter to health care providers on surgical mask and gown conservation strategies](#) as well as an updated [medical glove conservation strategy](#). Conservation strategies are outlined for conventional capacity, contingency capacity and crisis or alternate strategies. The FDA is collaborating with manufacturers of surgical masks and gowns to better understand the current supply chain issues related to the COVID-19 outbreak, and to avoid any widespread shortages of these products.

Information for Specific Populations

Extension of Employee Benefit Plans: The Department of Labor [notice](#), jointly issued with the Department of the Treasury and Internal Revenue Service, extends certain time frames affecting participants' rights to healthcare coverage, portability and continuation of group health plan coverage under COBRA, and extends the time for plan participants to file or perfect benefit claims or appeals of denied claims. These extensions provide participants and beneficiaries of employee benefit plans additional time to make important health coverage and other decisions affecting their benefits during the coronavirus outbreak.

Smoking and COVID-19: As part of its work to help protect public health, FDA [updated its FAQ page](#) with information about smoking and COVID-19. Smoking cigarettes can leave smokers more vulnerable to respiratory illnesses such as COVID-19, which is why there's never been a better time to quit smoking. FDA's [Every Try Counts](#) campaign has supportive tips and tools to help smokers get closer to quitting for good.

Research on COVID and Older People: AHRQ published a paper on [COVID-19 and the Safety of Older People](#). The paper highlights key patient safety problems, tools and resources for nursing homes, and professional organization resources.

Keeping Children Healthy: CDC updated their information on [Keeping Children Healthy While School's Out](#). The guidance includes steps to keep children healthy, signs to look for if children are sick, and how to help them continue learning. The CDC [FAQ document](#) with information for children was updated as well.