

HHS COVID-19 Update – May 15, 2020

Today, the Trump Administration announced the appointment of Moncef Slaoui as chief advisor and General Gustave F. Perna as chief operating officer of [Operation Warp Speed \(OWS\)](#), the administration’s national program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures).

Dr. Slaoui’s record certainly instills confidence – he led GlaxoSmithKline’s vaccine development division when it had the broadest portfolio of vaccines of any company—48—and created 14 new vaccines in ten years, including one I just had – Shingrix, to prevent shingles. General Perna is a four star, brings the “get-it-done” ethic of the military, and currently oversees the global supply chain and installation and materiel readiness for the entire U.S. Army.

These dynamic leads are joined by some of FDA, NIH, and DOD’s brightest stars (all named in the [press release](#)). Together, this Operation Warp Speed crew has January 2021 as their goal for having substantial quantities of a safe and effective vaccine available, among other objectives.

The [press release](#) is quite detailed about who, what, and how Operation Warp Speed will operate, including how they will coordinate as a public-private partnership, and do so in conjunction with no less than five federal agencies!

Now, I highlight one other item because some of you have asked about **Nursing Home Commission** announced by President Trump recently. Here’s more to know:

Call for Nominations for the Nursing Home Commission: CMS is announcing a [call for nominations for the new contractor-led Coronavirus Commission on Safety and Quality in Nursing Homes](#) to help inform immediate and future responses to the Coronavirus Disease 2019 (COVID-19) within these facilities. The Commission will conduct a comprehensive assessment of the overall response to the COVID-19 pandemic in nursing homes and will inform immediate and future actions to address the virus in order to safeguard the health and quality of life for an especially vulnerable population of Americans. The Commission will consist of a diverse group of individuals, which may include industry experts, clinicians, resident/patient advocates, family members of individuals residing in nursing homes, medical ethicists, nursing home administrators, academics, infection control and prevention professionals, state and local authorities, and other stakeholders whose expertise can contribute to one or more of the areas on which the Commission will focus. The contractor is accepting nominations on their Nursing Home Commission Nomination website, where additional information about the Commission and its purpose can also be found. The contractor has indicated that nominations will close on May 22, 2020 at 5:00 p.m. EDT, with announcement of the names of the Commission members occurring by the end of May.

Testing

Updated Information on the Accuracy of Abbott ID NOW Point-of-Care Test: FDA is alerting the public to early data that suggest potential [inaccurate results from using the Abbott ID NOW point-of-care test](#) to diagnose COVID-19. Specifically, the test may return false negative results. The FDA is sharing early information available about potential inaccurate results in the spirit of transparency. The agency has been working with Abbott to analyze the information gathered to date and has worked with the company on a customer notification letter to alert users that any negative test results that are not consistent with a patient's clinical signs and symptoms or necessary for patient management should be confirmed with another test.

Testing updates: During the COVID-19 pandemic, the FDA has worked with more than 390 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 98 tests under EUAs, which include 85 molecular tests, 12 antibody tests, and 1 antigen test.

Treatment

Expanding the Understanding of Sepsis and COVID-19: BARDA announced an expanded partnership with Beckman Coulter to [assess digital sepsis prediction solution](#) for COVID-19 patients. BARDA and Beckman Coulter, in collaboration with Dascena, Inc., are expanding a public-private partnership to support additional advanced research and development that will optimize a machine-learning-based sepsis prediction and detection algorithm to include assessing its use with COVID-19 patients.

Study Finds a Potential Treatment to Protect Against COVID-19 Pneumonia: NIH released information from a study with the findings that [Investigational ChAdOx1 nCoV-19 Vaccine Protects Monkeys Against COVID-19 Pneumonia](#). A single dose of ChAdOx1 nCoV-19, an investigational vaccine against SARS-CoV-2, has protected six rhesus macaques from pneumonia caused by the virus. The findings are not yet peer-reviewed but are being shared to assist the public health response to COVID-19. Based on these data, a Phase 1 trial of the candidate vaccine began on April 23 in healthy volunteers in the United Kingdom.

Ensuring Supply of Infusion Pumps and Their Accessories: The FDA issued an [Emergency Use Authorization \(EUA\)](#) for infusion pumps and infusion pump accessories that, among other things, meet certain safety, performance, and labeling criteria, in response to concerns relating to the insufficient supply and availability of the devices for use by healthcare providers in the continuous infusion of medications, total parenteral nutrition, and/or other fluids into patients during the COVID-19 pandemic. Infusion pumps and accessories that have been confirmed by FDA to meet the criteria will be added to the letter of authorization in Appendix A. A manufacturer may request the addition of any eligible infusion pump and/or infusion pump accessory to Appendix A by submitting a request to CDRH-COVID19-InfusionPumps@fda.hhs.gov, as outlined in the EUA.

PPE

Guidance for Pharmacy Compounders with PPE Shortages: The FDA issued an update to its [guidance for pharmacy compounders](#) that experience shortages of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. In the update, FDA has clarified that drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom, when specific beyond-use dates are utilized. FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available. As a temporary measure during the public health emergency posed by COVID-19, or until FDA otherwise withdraws or revises this guidance, and while PPE shortages impact compounding operations, FDA does not intend to take enforcement action regarding compliance with the insanitary conditions provision when drugs intended or expected to be sterile are compounded without standard PPE provided that specific circumstances exist.

Information for Specific Populations

Uplifting Families During COVID-19: ACF Administrator Lynn Johnson published an [op-ed](#) discussing how ACF has responded to help uplift those most impacted by the COVID-19 pandemic. She highlights actions taken to ensure PPE for child welfare workers, extended the use of Head Start Centers for child care for essential workers, and urged child welfare legal and judicial leaders to work together to ensure that necessary court hearings continue during this pandemic.

Information for General Population Shelters during COVID-19: CDC released [CDC Interim Guidance for General Population Disaster Shelters During the COVID-19 Pandemic](#). This interim guidance is based on current information about the transmission and severity of coronavirus disease 2019 (COVID-19). 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 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.

Information for Immunocompromised Populations: CDC updated their information for [If You Are Immunocompromised, Protect Yourself From COVID-19](#). People with weakened immune systems are at higher risk of getting severely sick from SARS-CoV-2, the virus that causes COVID-19. They may also remain infectious for a longer period of time than others with COVID-19, but we cannot confirm this until we learn more about this new virus. The information includes tips on preventing COVID-19, steps you can take to protect your health, treatment, and additional information for specific conditions and risk factors.

Information for Meat and Poultry Processing Workers and Employers: CDC and OSHA updated their guidance for [Meat and Poultry Processing Workers and Employers](#). The guidance includes exposure risk among workers, and detailed information on creating an assessment and control plan to prevent an outbreak.

Information for Veterinary Clinics: CDC updated their [Interim Infection Prevention and Control Guidance for Veterinary Clinics Treating Companion Animals During the COVID-19 Response](#). Specific updates include the addition of a section on PPE extended use and reuse.

Information for Non-US Healthcare Settings: CDC updated their [Operational Considerations for Containing COVID-19 in non-US Healthcare Settings](#). To facilitate implementation of WHO COVID-19 technical guidance on infection prevention and control (IPC) activities for countries, CDC has developed operational considerations to help contain and prevent COVID-19 in healthcare facilities in non-US settings. These documents were created for healthcare facilities with limited resources (such as staff shortages and supply shortages), particularly in low- and middle-income countries.

CMS Updates

Information for Medicare Fee-for-Service Providers: CMS updated their [FAQ document on Medicare Fee-for-Service Billing](#). Generally, the FAQs regard Medicare and Medicaid Programs' and policy and regulatory revisions in response to COVID-19 public health emergency. The updated question relates to accountable care organizations and the Shared Savings program.

CMS Gives States Additional Flexibility to Address Coronavirus Pandemic

CMS has approved over 190 requests for state relief in response to the COVID-19 pandemic, including recent approvals for California, Georgia, Indiana, Minnesota, Missouri, New Mexico, Ohio, and Rhode Island. These approvals help to ensure that states have the tools they need to combat COVID-19. This is done through a wide variety of waivers, amendments, and Medicaid state plan flexibilities, including support for programs that care for the elderly and people with disabilities. CMS also developed a [toolkit](#) to expedite the application and review of each request and has approved these requests in record time. These approved flexibilities support President Trump's commitment to a COVID-19 response that is locally executed, state managed, and federally supported.

Research and Data

COVID-19 and Health Disparities Research: NIH director released a blog on [COVID-19 Brings Health Disparities Research to the Forefront](#). The coronavirus 2019 (COVID-19) pandemic has brought into sharp focus many of the troubling things that we already knew about health disparities in the United States but have failed to address. With the bright light now shining on this important issue, it is time to talk about the role research can play in reducing the disproportionate burden of COVID-19, as well as improving the health of all people in our great nation. In the blog, Dr. Collins and the Dr. Eliseo Pérez-Stable, Director of NIH's National Institute on Minority Health and Health Disparities (NIMHD) discuss the current data on the disproportionate impact of COVID-19 on minority populations and what NIH is doing to address health disparities from a research perspective.

Updates from COVIDView: CDC released their weekly [COVIDView](#) update. Nationally, levels of influenza-like illness (ILI) and COVID-19-like illness (CLI) and the percentage of specimens testing positive for SARS-CoV-2, the virus that causes COVID-19, continue to

decline. Mortality attributed to COVID-19 also decreased compared to last week but remains elevated above baseline and may increase as additional death certificates are counted.

Update from COVID Forecasts: CDC released their weekly analysis of the [Forecasts for Cumulative Deaths](#). This week's national-level forecasting includes 12 individual forecasts, and all indicate an increase in deaths in the coming weeks. Predicted rates of increase differ among the forecasts, depending on assumptions about the strength and coverage of social distancing behaviors. The National Ensemble Forecast suggests that the number of cumulative reported deaths are likely to exceed 100,000 by June 1st. State-level ensemble forecasts indicate that states with low numbers of deaths reported to date are not likely to see a rapid rise in the coming weeks, while states with high numbers of deaths reported to date are likely to see substantial increases.

National Hospital Week: May 10 through 16, 2020, marks National Hospital Week. HHS Secretary Azar [notes](#) that "...Everyone who staffs America's hospitals—from doctors and nurses to everyone who keeps these institutions clean and supplied—has worked tirelessly and heroically to keep America's hospitals running and patients cared for. America's hospitals and their workers have been stressed, but through dedication and creativity, they have not been overwhelmed.... Through the most trying time our healthcare system has ever faced, we will continue helping America's hospitals meet this emergency and get Americans the care they need."