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HHS COVID-19 April 16, 2020 Update

Today the President hosted a call with the nation's governors, discussing a framework for reopening America. Almost every governor in the country participated, indicating their keen interest in this topic, and discussion went for almost two hours. Following that, during the evening's press conference, the President and his Task Force unveiled Guidelines for Opening Up America Again, a three-phased approach based on the advice of public health experts. These steps will help state and local officials when reopening their economies, getting people back to work, and continuing to protect American lives. The President reiterated that governors will be the decision makers on timing and scope of reopening their state; the Task Force guidelines are meant to support their decisions by offering recommendations, criteria, and benchmarks for states to consider.

Other resources from the press conference include a fact sheet. President Trump remains a tireless fighter for the American people and will continue to take decisive actions to keep our Nation healthy and prosperous.

Today's HHS news on COVID-19 follows.

Testing and Treatment

New Resource to Find Public Health and Testing Information: The White House announced a new collaboration by Schema.org to help Americans find the most up-to-date public health guidance and the most relevant information on testing facilities in their communities. Standard tags were created that can be added to any website's code, making it easier to find COVID-19 prevention measures, disease spread statistics, quarantine rules and travel guidance, and testing information through online search engine results. All federal websites will incorporate these new Schema.org standard tags. The private sector, state and local governments, and the academic community are encouraged to do the same.

Donating Blood Plasma: FDA is putting out a call to donate blood plasma for recovered COVID-19 patients. Convalescent plasma is an antibody-rich product made from blood donated by people who have recovered from the disease caused by the virus. Prior experience with respiratory viruses and limited data that have emerged from China suggest that convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19. It is important to evaluate this potential therapy in the context of clinical trials, through expanded access, as well as facilitate emergency access for individual patients, as appropriate. The FDA has launched a new webpage to guide recovered COVID-19 patients to local blood or plasma collection centers to discuss their eligibility and potentially schedule an appointment to donate. The webpage also provides information for those interested in participating in the

expanded access protocol, conducting clinical trials or submitting eIND applications. The American Red Cross has also set up a website for interested donors and the FDA continues to work with others in this area to help encourage additional donations. Additionally, BARDA and the American Red Cross (ARC) are collaborating on systems and procedures to recruit donors who have recovered from COVID-19. Through this collaboration the ARC will prepare procedures for the collection of plasma for investigational use in treating patients infected with COVID-19.

Expanding Availability of Systems to Measure Body Temperature: FDA issued an immediately-in-effect guidance that provides a policy to help expand the availability of telethermographic systems used for body temperature measurements for triage use for the duration of the public health emergency. The advantage of using telethermographic systems for initial temperature assessment for triage use is the potential use in high throughput areas (e.g., airports, businesses, warehouses, factories) and in settings where other temperature assessment products may be in short supply. FDA believes the policy set forth in this guidance may help address urgent public health concerns raised by shortages of temperature measurement products by helping to clarify the regulatory landscape and expand the availability of telethermographic systems used for initial body temperature measurements for triage use during this public health emergency.

Policy for Compounding Drugs: FDA issued an immediately-in-effect guidance that communicates temporary policy for the compounding of certain human drug products for hospitalized COVID-19 patients by registered outsourcing facilities. Some hospitals are experiencing difficulties accessing drug products used for patients with COVID-19. In addition, due to the large number of persons infected with COVID-19 and subsequent hospitalizations, it is possible that other drug products may become harder to acquire. To help the situation, the FDA will allow specific medicines that are used to aid people on ventilators to be compounded in bulk.

Rapid Diagnostic Test: BARDA is collaborating with Hememics Biotechnologies, Inc. on the development of a rapid, Bluetooth-connected SARS-CoV-2 diagnostic test. The test is being designed to detect SARS-CoV-2 antigen from nasal swab samples and associated antibodies in 60 seconds or less through a finger-prick. Using the nasal swab antigen test, healthcare providers can triage patients infected with SARS-CoV-2 rapidly and make informed treatment decisions. Furthermore, antibody testing of blood to identify serological antibodies indicates which patients have been previously infected, even without showing symptoms, and recovered or those who could be potentially developing an infection but asymptomatic and need care. The added convenience of this test being Bluetooth-connected to cloud-based data management networks may aid public health officials with real-time geographical mapping of outbreaks.

Vaccine Update: BARDA and Sanofi Pasteur, the vaccines global business unit of Sanofi, are expanding their collaboration to develop a SARS-CoV-2 vaccine. The previously announced research for a COVID-19 vaccine using a recombinant DNA platform will accelerate into non-clinical studies and a Phase 1 clinical trial to demonstrate initial safety and efficacy of the vaccine candidate. The technology was developed with BARDA support to make millions of

doses of vaccine quickly in an influenza pandemic, and Sanofi uses the platform for its FDA-licensed seasonal influenza recombinant vaccine.

Serology Tests: The FDA issued two new emergency use authorizations (EUAs) for serology tests to detect for the presence of coronavirus antibodies. The EUAs were issued to Ortho-Clinical Diagnostics, Inc. for its VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and Chembio Diagnostic Systems, Inc. for its DPP COVID-19 IgM/IgG System.

Contact Tracing App: NIH funded MD2K who launched the new mobile app, called mContain, for download by residents of the greater metropolitan area of Memphis, Tennessee. Once downloaded and installed on a personal mobile device, the mContain app collects location traces and sends notifications to users if they have had a recent encounter with a COVID-19 positive individual. The app reduces the chance of community transmission by providing an early warning to users who may be at the risk of infection from a COVID-19 positive individual. The mContain app provides two primary alert services: it can give users crowding information and provide notification to users who have had contact with a COVID-19-positive individual. The crowding alert feature provides information that should encourage social distancing within the community, indicating concentrations of users. The contact alert is expected to anonymously reduce community transmission of the COVID-19 virus and other infectious diseases. The data necessary to inform the app about positive test results is collected voluntarily.

Warnings Against Fraud: The FDA and Federal Trade Commission (FTC) issued a warning letter to one company for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The seller warned, Earth Angel Oils, offers essential oil products that are unapproved and misbranded drugs for the prevention and treatment of COVID-19. 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.

Diagnostics Update to Date: During the COVID-19 pandemic, the FDA has worked with more than 315 test developers who have said they will be submitting emergency use authorization (EUA) requests to FDA for COVID-19 tests. To date, 36 emergency use authorizations have been issued for COVID-19 tests. The FDA has been notified that more than 190 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.

Summary of FDA Actions: The FDA has posted a new "At-a-Glance Summary" that captures the agency's major activities in the fight against COVID-19. The agency intends to regularly update this resource on efforts related to medical products and equipment, vaccines and therapeutics, food supply and more.

PPE and Supplies

Expanding Ventilator Supply: HHS announced a new contract for ventilator production rated under the Defense Production Act (DPA), to General Electric (GE), in partnership with Ford.

GE's contract, at a total contract price of $336 million, is for 50,000 ventilators to be produced by July 13. In total, combined with contracts announced this month, HHS has finalized contracts to produce or acquire more than 41,000 ventilators by the end of May, and over 187,000 ventilators by the end of the year.

Reuse of N-95 Respirators: NIH released results of their study that validates decontamination methods for re-use of N95 respirators. N95 respirators can be decontaminated effectively and maintain functional integrity for up to three uses, according to National Institutes of Health scientists. The study was conducted in a controlled laboratory setting and the findings are not yet peer-reviewed but are being shared to assist the public health response to COVID-19. Decontamination methods tested included vaporized hydrogen peroxide (VHP), 70-degree Celsius dry heat, ultraviolet light, and 70% ethanol spray. The authors concluded that VHP was the most effective decontamination method, because no virus could be detected after only a 10-minute treatment. UV and dry heat were acceptable decontamination procedures as long as the methods are applied for at least 60 minutes.

Decontaminating Respirators: The FDA issued an emergency use authorization (EUA) for the emergency use of Stryker Instrument's Sterizone VP4 Sterilizer1 N95 Respirator Decontamination Cycle for use in decontaminating compatible N95 and N95-equivalent respirators for single-user reuse by healthcare personnel.

Information for Specific Populations

Crisis Standards of Care and Civil Rights Law: ASPR released a document on crisis standards of care which is intended to provide information about crisis standards of care in a resource constrained setting, such as the COVID-19 pandemic, to state, local, tribal, and territorial policymakers, healthcare systems leadership, and other decision-makers. Certain jurisdictions may be developing or implementing potentially discriminatory policies that negatively impact vulnerable populations (e.g., older adults and persons with disabilities). These policies are addressing the application of crisis standards of care in resource-constrained settings in the context of the COVID-19 pandemic. OCR also announced that they have resolved a complaint filed against the Pennsylvania Department of Health (PDH) after PDH revised its Interim Pennsylvania Crisis Standards of Care for Pandemic Guidelines (CSC Guidelines) to ensure that persons will not be discriminated against based on disability if providers in the state were to begin triaging life-saving health care services. This is the second enforcement action OCR has taken since OCR issued a Bulletin reminding covered entities of the continued applicability of civil rights laws during the COVID-19 public health emergency.

Considerations for Pharmacies: CDC updated their guidance on Considerations for Pharmacies. Recommendations include: everyone entering the pharmacy should wear a face covering, regardless of symptoms; cloth face coverings should not be placed on young children under age 2, anyone who has trouble breathing, or is unconscious, incapacitated or otherwise unable to remove the mask without assistance; pharmacists and pharmacy technicians should always wear a facemask while they are in the pharmacy for source control; postponement and reschedule delivery of some routine clinical preventive services, such as adult immunizations,

which require face to face encounters; and special considerations for clinics that are co-located in pharmacies.

FAQs on FFCRA and CARES Act: CMS posted an FAQ document with multiple questions on how the relief legislation applies to Medicare and Medicaid programs. Topics include the emergency period, new optional Medicaid group, benefits and cost-sharing for COVID-19 testing and diagnostic services, implications for CHIP, BHP and other questions.

FAQs for Clinicians: CDC has updated their FAQ document for healthcare professionals. Topics include COVID-19 risk, transmission, testing, diagnosis and notification, treatment and management, obstetrical care, drug and investigational therapies, waste management and additional resources.

Guidance on Cleaning and Disinfecting Vehicles and Facilities: CDC released recommendations for Non-emergency Transport Vehicles that May Have Transported Passengers with Suspected/Confirmed COVID-19. People who are known or suspected to have COVID-19 may use non-emergency vehicle services, such as passenger vans, accessible vans, and cars, for transportation to receive essential medical care. The guidance includes recommendations on how to clean different areas of the vehicle and at a minimum, recommends owners to clean and disinfect commonly touched surfaces in the vehicle at the beginning and end of each shift and between transporting passengers who are visibly sick. CDC's guidance on Cleaning and Disinfecting Your Facility includes everyday steps, steps when someone is sick, and considerations for employers.

CMS Hospital Payment and Inpatient Rehabilitation Facility Waivers: CMS issued guidance implementing the CARES Act that impacts inpatient prospective payment system hospital payment and provides new flexibilities for inpatient rehabilitation facilities and long-term care hospitals. The Coronavirus Aid, Relief, and Economic Security (CARES) Act increases payment for Inpatient Prospective Payment System (IPPS) and long-term care hospital (LTCH) inpatient hospital care attributable to COVID-19. CMS provided guidance for IPPS hospitals and LTCHs on how to code claims to receive the higher payment. The CARES Act also waives the requirement that Medicare Part A fee-for-service patients treated in inpatient rehabilitation facilities receive at least 15 hours of therapy per week. During the public health emergency period, LTCHs will be paid at higher rates and will not be penalized for accepting patients that would not typically be treated at an LTCH. CMS also updated their summary of emergency declaration blanket waivers for healthcare providers.

Guidance to Assist with Grief Management: ASPR has posted resource documents to assist with the management of grief. The resources include Tips for Healthcare Workers Managing Grief and Recommendations for How to Handle the Death of a Colleague during COVID-19,

Resources for Programs Providing Treatment for Opioid Use Disorder: The document lists guidance and resources for in-patient and out-patient programs and facilities providing Medication Assisted Treatment (MAT) for individuals with opioid use disorder (OUD). These resources are available to provide continuity of care and to help mitigate the potential surge of

patients seeking inhospital treatment. Resources are continually changing; visit the Substance Abuse and Mental Health Services Administration (SAMHSA) COVID-19 website for the most recent information.

Suspension of 2% Payment Adjustment for Medicare FFS Claims: The Centers for Medicare & Medicaid Services (CMS) recently issued guidance implementing Section 3709 of the Coronavirus Aid, Relief, and Economic Security Act, which temporarily suspends the 2% payment adjustment currently applied to all Medicare Fee-For-Service (FFS) claims due to sequestration. The guidance notes that the suspension is effective for FFS claims with dates of service from May 1 through December 31, 2020.

CMS Waiver Flexibility Update: CMS has approved 52 COVID- related emergency waivers, 31 state amendments, 11 COVID-related Medicaid Disaster Amendments and one CHIP COVID-related Disaster Amendment in record time. CMS recently approved two additional COVID-related emergency Medicaid waivers, delivering urgent regulatory relief to ensure the Commonwealth of Puerto Rico and the Commonwealth of the Northern Mariana Islands can quickly and effectively care for their most vulnerable citizens. CMS also approved COVID-related Medicaid Disaster Amendments that bring relief to Arkansas and Rhode Island. These approvals help to ensure that states have the tools they need to combat COVID-19 through a wide variety of state plan flexibilities. CMS continues to authorize amendments to ensure emergency flexibilities in programs that care for the elderly and people with disabilities, including most recently for Colorado, Louisiana and Nevada. These approved flexibilities support President Trump's commitment to a COVID-19 response that is locally executed, state managed, and federally supported.

Not HHS, but relevant for healthcare:
FCC COVID-19 Telehealth Program. The Federal Communications Commission (FCC) just approved an Order to create a $200 million telehealth program to support healthcare providers responding to the ongoing coronavirus pandemic, using funds appropriated as part of the CARES Act. The COVID-19 Telehealth Program will help healthcare providers purchase telecommunications, broadband connectivity, and devices necessary for providing telehealth services. Applications from healthcare providers will be accepted and processed on a rolling basis as soon as application forms are published in the Federal Register. Details on information that applications must include are on page 14 of the Order.