HHS COVID-19 Update - May 4, 2020

Testing Updates

Improving Antibody Testing Quality: FDA has revised its policy to improve antibody testing quality. 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. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States. Under the new policy, FDA expects commercial manufacturers to submit Emergency Use Authorization (EUA) requests, including their validation data, within 10 days of publication of the updated policy or the date they notify FDA of their test validation, whichever is later. Additional information can be found in a fact sheet on antibody testing oversight and use for COVID-19, as well as in a blog posting that notes the new emphasis on prioritizing access and accuracy.

Contact Tracing Training Guidance: CDC released a training module on contact tracing. This web page contains a sample training plan including training topics that may be helpful for state and local public health jurisdictions to consider when designing their own training plan for COVID-19 contact tracers. Each heading represents the learning objective for that section. Suggested training modalities/formats are provided, as well as information about sample existing trainings and resources. This document may be updated as new resources become available.

Information on Evaluation and Testing Patients: CDC updated their guidance on evaluating and testing persons for COVID-19. The changes include updated recommendations for testing, specimen collection, and reporting patients and reporting positive test results, and specification of testing priorities.

CDC Resources for Testing: CDC released a new fact sheet on federal resources for COVID-19 contact tracing staff. This fact sheet describes several ways health departments can access additional staffing for COVID-19 contact tracing, including through State Service Commissions and AmeriCorps Programs, CDC, and FEMA.

Information for Laboratories: CDC updated their FAQ document for testing and reporting by laboratories. The FAQs include information on accessing laboratory testing, data and reporting, test developers, serology, and ordering supplies.

Treatment Updates

Symptom Based Strategy for Discontinuing Isolation: CDC released a decision memo that outlines the updated recommendations for discontinuing isolation. In the context of community transmission where continued testing is impractical, available evidence at this time indicates that an interim strategy based on time-since-illness-onset and time-since-recovery can be implemented to establish the end of isolation. Practical application of a symptom-based strategy cannot prevent all infections.

Updated Information on Discontinuing Isolation: CDC also updated their discontinuation of isolation for persons with COVID-19 not in healthcare settings. This guidance is for healthcare providers and public health officials managing persons with COVID-19 under isolation who are not in healthcare settings. This includes, but is not limited to, at home, in a hotel or dormitory room, or in a group isolation facility. Updates include extending the home isolation period based on evidence suggesting a longer duration of viral shedding and will be revised as additional evidence becomes available. The clinical care guidance for health professionals and information on what to do if you are sick was also updated to reflect this change.

Updates on Convalescent Plasma: The FDA updated its guidance on convalescent plasma and associated web page. The updated guidance provides clarification for investigators on how to submit investigational applications for COVID-19 convalescent plasma. In addition, the guidance includes updated information regarding potential donors. Previously, the FDA's guidance noted that to qualify, individuals should have complete resolution of symptoms for 28 days or resolution for 14 and a negative diagnostic test. The revised guidance recommends that individuals have complete resolution of symptoms for at least 14 days prior to donation. A negative lab test for COVID-19 disease is not necessary to qualify for donation. The revised guidance also clarifies that FDA does not recommend storing a retention sample from the convalescent plasma donation for single patient emergency INDs.

Expanding Dialysis Therapy Options: To help address shortages of continuous renal replacement therapy (CRRT) products during the COVID-19 public health emergency, today the FDA issued an EUA to Fresenius Medical Care for emergency use of the multiFiltrate PRO System and multiBic/multiPlus Solutions. CRRT is a type of dialysis therapy used to filter and clean the blood when the kidneys are damaged or are not functioning normally. The Fresenius multiFiltrate PRO System and multiBic/multiPlus Solutions have been authorized to provide CRRT to treat patients in an acute care environment during the COVID-19 public health emergency.

Additional Information on Remdesivir: FDA released Frequently Asked Questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients. The FAQs cover EUA for the drug, the side effects, additional information about the uses and the study on Remdesivir and how to obtain the drug.

Convalescent Plasma Guidance and Recommendations: FDA updated their general guidance and recommendations on convalescent plasma. The guidance includes recommendations on pathways for use of plasma, patient eligibility, collection of convalescent plasma, and recordkeeping. Because COVID-19 convalescent plasma has not yet been approved for use by

FDA, it is regulated as an investigational product. A health care provider must participate in one of the pathways described below. FDA does not collect COVID-19 convalescent plasma or provide COVID-19 convalescent plasma. Health care providers or acute care facilities should instead obtain COVID-19 convalescent plasma from an FDA-registered blood establishment.

New Study on Coronavirus and Children: NIAID announced a new study to determine incidence of novel coronavirus infection in US children. The study, called Human Epidemiology and Response to SARS-CoV-2 (HEROS), also will help determine what percentage of children infected with SARS-CoV-2, the virus that causes COVID-19, develop symptoms of the disease. In addition, the HEROS study will examine whether rates of SARS-CoV-2 infection differ between children who have asthma or other allergic conditions and children who do not.

PPE and Supplies

PPE Shipments to Nursing Homes: FEMA has released additional details in a fact sheet on PPE shipments to nursing homes. Announced last week, FEMA will coordinate two shipments totaling a 14-day supply of personal protective equipment (PPE) to more than 15,000 nursing homes across the Nation. Shipments are expected to begin in the first week of May and a second shipment will occur in June. Each facility will receive an allotment of surgical masks, gloves, goggles, and gowns. Each facility will receive an allotment of all four items based on the staff size of the facility.

Funding and Resources

\$40 Million to Support Education to Racial and Ethnic Minority and VulnerableCommunities: The Office of Minority Health announced a competitive funding opportunity to invest up to \$40 million for the development and coordination of a strategic network of national, state, territorial, tribal and local organizations to deliver important COVID-19-related information to racial and ethnic minority, rural and socially vulnerable communities hardest hit by the pandemic. The information network will strengthen efforts to link communities to COVID-19 testing, healthcare and social services and to best share and implement effective response, recovery and resilience strategies. Applications are due by 6:00 PM Eastern Time on Monday, May 11.

30 States Receive Assistance for Crisis Counseling: FEMA announced approval of 30 states and the District of Columbia for its Crisis Counseling Assistance and Training program. The program helps fund state-provided crisis counseling services to residents struggling with stress and anxiety as a result of the coronavirus (COVID-19) pandemic. FEMA's Crisis Counseling program helps people and communities to recover from the effects of natural or man-made disasters through short-term interventions that provide emotional support, crisis counseling, and connection to familial and community support systems.

\$200 Million to Local Jurisdictions for Hungry and Homeless Populations: FEMA announced \$200 million in supplemental funding allocations to local jurisdictions across the

country to supplement local service organizations that provide critical resources to people with economic emergencies, which include our hungry and homeless populations.

Information for General Populations:

COVID-19 At a Glance: The FDA has also posted an updated COVID-19 Response At-A-Glance Summary. It contains updates on major agency activities as well as some important facts and figures.

Tips about Grocery Shopping: Given the many questions people have about grocery shopping safety, the FDA has posted a video, 12 Tips for Grocery Shopping During the Pandemic, to advise consumers.

Information for Specific Populations:

Tips for Healthcare Systems to Operative Effectively: CDC released a new document with 10 ways healthcare systems can operative effectively during the covid-19 pandemic. This document provides practical approaches that can be used to protect healthcare personnel (HCP), patients, and communities. The tips include information on work safety and support, patient service delivery, data streams for situational awareness, facility practices and communications.

Information on Caring for Someone at Home: CDC updated their information on Caring for Someone Sick at Home or other non-healthcare setting. The guidance includes information on how to protect yourself and others. Advice includes learning what to do when someone has symptoms of COVID-19 or when someone has been diagnosed with the virus. This information also should be followed when caring for people who have tested positive but are not showing symptoms.

Information for Pediatric Healthcare Providers: CDC updated their resources for Pediatric Healthcare Providers on what to do when managing pediatric patients with suspected or confirmed COVID-19. The webpage has information on maintaining childhood immunizations during the pandemic, the burden of COVID-19 among children, the clinical presentation of COVID-19 in children, treatment and prevention for children, and additional resources.

Information for Businesses: CDC updated their FAQ document for businesses. The FAQs cover topics including suspected or confirmed cases in the workplace, reducing the spread in workplaces, healthy business operations, cleaning and disinfecting, critical infrastructure and additional resources.

Information for Dentists: CDC updated their infection prevention and control guidance for dental settings during the COVID-19 response. The key information notes that dental settings have unique characteristics that warrant additional infection control considerations and advises dentists to postpone elective procedures, surgeries, and non-urgent dental visits, proactively communicate to both staff and patients the need for them to stay at home if sick, and know steps

to take if a patient with COVID-19 symptoms enters your facility. CDC recommends dentists actively screen patients and colleagues before every shift.

Information for Community and Faith-based Organizations: CDC updated their information for community and faith-based organizations in preparations for re-opening. The resources include information on ongoing mitigation guidance, prevention and support, and a webinar.

Information for Veterinarians regarding Companion Animals: CDC updated their interim infection prevention and control guidance for veterinary clinics treating companion animals during the covid-19 response. Updates were made to clarify PPE recommendations based on situational risk factors and guidance for returning to normal clinic practices.

Information for Environmental Health Practitioners: CDC posted information for specific environmental health practitioners including congregate facilities and shelters such as general population disaster shelters, correctional and detention facilities, retirement communities, childcare centers that remain open, cooling centers and more. This webpage provides information for environmental health practitioners from CDC and other trusted sources.