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HHS COVID-19 Update – June 3, 2020

Funding

$250 Million for U.S. Health Care Systems: HHS and ASPR are providing an additional $250 million to aid U.S. health care systems treating patients and responding to the COVID-19 pandemic. As authorized by the CARES Act, HHS has now provided a total of $350 million to health care systems for pandemic response, including $100 million released in April 2020. The funds will support hospitals and other health care entities to train workforces, expand telemedicine and the use of virtual healthcare, procure supplies and equipment, and coordinate effectively across regional, state and jurisdictional, and local health care facilities. This funding will also advance the mission of the National Special Pathogen System to enhance national capacity and capability to respond to highly infectious diseases now and in the future.

$20.3 Million to Expand Addiction Workforce in Underserved Communities: HHS awarded $20.3 Million to Expand the Addiction Workforce in Underserved Communities through HRSA. This money was awarded to 44 recipients to increase the number of fellows at accredited addiction medicine and addiction psychiatry fellowship programs. The awardees will train addiction specialists at facilities in high need communities that integrate behavioral and primary care services. This new funding addresses a serious need that could be exacerbated by the COVID-19 pandemic.

Testing

Rapid Diagnostic Test: BARDA announced that is collaborating with Quidel Corporation to develop a rapid multi-plex diagnostic test to detect the SARS-CoV-2 virus within an hour. Results are provided to users and integrated into a cloud-based mobile platform that can convey de- identified test results to public health agencies. This capability could help public health departments monitor the spread of COVID-19 infections, and take action to help decrease the number of infections in their communities. The test will also simultaneously detect and distinguish other viruses apart from SARS- CoV-2 including respiratory syncytial virus (RSV), influenza A, and influenza B.

Automated Total Antibody Test: BARDA announced partnership with Siemens Healthineers to develop automated total antibody test for COVID-19. This laboratory-based total antibody test can be used to detect the presence of both SARS-CoV-2 IgM and the longer-lasting IgG antibodies in human serum and plasma. Serology-based tests like the SARS-CoV-2 total antibody test can be used as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating a recent or prior infection.

Testing Updates: During the COVID-19 pandemic, the FDA has worked with more than 400 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 119 tests under EUAs, which include 103 molecular tests, 15 antibody tests, and 1 antigen test.

Treatment

Clinical Care Guidance: CDC updated the interim guidance is for clinicians caring for patients with confirmed infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 2019 (COVID-19). The guidance includes clinical presentation, clinical course, laboratory and radiographic findings, discontinuation of transmission-based precautions or home isolation and additional resources.

NASA Ventilator Approval: The FDA added a second ventilator developed by NASA to the list of authorized ventilators, ventilator tubing connectors and ventilator accessories under the ventilator emergency use authorization (EUA) that was issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in health care settings to treat patients during the COVID-19 pandemic. The NASA VITAL (Ventilator Intervention Technology Accessible Locally) is intended to last three to four months and is specifically tailored to provide respiratory support for COVID-19 patients who are experiencing respiratory failure or insufficiency. Where the first NASA ventilator relied on wall gas as the pressure source, the second ventilator uses an internal compressor for its energy source. The device is designed to be built with components outside the current medical device supply chain and therefore does not impact the existing supply chain of currently made ventilators.

Emergency Resuscitator Approval: The FDA added an emergency resuscitator for the Fitbit Flow to the list of authorized ventilators, ventilator tubing connectors and ventilator accessories under the ventilator emergency use authorization (EUA). The Fitbit Flow is a continuous respiratory support system that includes an FDA-cleared Manual Resuscitator. The accessory is an AMBU bag with audible and visual alarms that aid the performance of the manual resuscitator for continuous breathing. This design is intended for use in treating patients with COVID-19.

IHS Critical Care Response Team: IHS announced that a Critical Care Response Team to further enhance patient access across the Indian Health Service. Critical Care Response Team of expert physicians, registered nurses, and other healthcare professionals will be used on an as needed basis to provide urgent lifesaving medical care to COVID-19 patients admitted to IHS or tribal hospitals.

Easing Process for Development of Pediatric Treatment and Prevention Products: The FDA, in collaboration with the European Medicines Agency (EMA), provided procedural assistance to sponsors and applicants who anticipate submission of pediatric product development plans for the treatment and prevention of COVID-19. In issuing this Common Commentary, the FDA and EMA aspire to streamline administrative processes and facilitate

efficient submission of an initial Pediatric Study Plan (iPSP) and Paediatric Investigation Plan (PIP).

Increasing Supply of Alcohol-Based Hand Sanitizer: FDA has taken additional action to help ensure widespread access to hand sanitizers during the COVID-19 public health emergency. The guidance provides additional clarification on the manufacturing and compounding of certain alcohol-based hand sanitizer products to help ensure that harmful levels of impurities are not present in ethanol used in hand sanitizer.

Updated Guidance for Institutional Review Boards: The FDA published guidance, titled Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency Guidance for IRBs and Clinical Investigators, which includes recommendations regarding procedures for single IRB member review. This is in response to physician requests for a waiver from the requirement for full IRB review. The guidance recommendations also address factors to consider when assessing potential benefits and risks for a particular patient being treated under expanded access.

Reopening Information

Keeping Public Spaces Safe: CDC released a fact sheet on Keeping Workplaces, Homes, Schools or Commercial Establishments Safe. This is a print resource on what every American and community can do now to decrease the spread of coronavirus.

Information for Schools and Child Care Programs: CDC updated their FAQS for K-12 Schools and Child Care Programs. Updates include additional information about administration of asthma peak flow meters in school settings.

Resources for Hospitals During Civil Unrest: ASPR released a document on Resources for Hospitals During Civil Unrest. The document outlines existing resources and documents to assist and protect hospitals providing care during civil unrest.

Healthcare System Preparedness for Secondary Disasters: ASPR released a resource on Healthcare System Preparedness for Secondary Disasters during COVID-19. Secondary disasters (e.g., natural disasters, cyberattacks, large-scale transportation accidents, mass casualty incidents) that strike during the COVID-19 pandemic will further stress the health and medical system and threaten vulnerable residents and infrastructure. Below are considerations for healthcare and emergency management professionals when planning for allhazard secondary disasters during a public health emergency.

Visitation Guidance for Retirement Communities: ASPR released COVID-19 Visitation Guidance for Retirement Communities. Based on CDC guidance, ASPR notes that Retirement communities and independent living facilities should consider limiting visitation. For example, each resident should be limited to one visitor per day. Restrictions should be in place for any

visitors who recently traveled or have symptoms of COVID-19. Children should be separated as much as possible from individuals who are at particularly high risk for severe illness from COVID-19.

Information for Specific Populations

Resources for Health Professionals: The FDA recognizes the vital role of health professionals in the fight against COVID-19. In order to help health professionals quickly and easily access FDA resources, we created a new web page, titled Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals. This page contains links to FDA emergency use authorizations; information about personal protective equipment and other medical products for use during COVID-19.

Information for Healthcare Professionals: CDC updated their Information for Healthcare Professionals about COVID-19. The webpage includes information on caring for patients, protecting patients and workers, facility guidance and additional resources.

Information on How Coronavirus Spreads: CDC updated their information on How COVID-19 Spreads. COVID-19 is thought to spread mainly through close contact from person-to-person. Some people without symptoms may be able to spread the virus. We are still learning about how the virus spreads and the severity of illness it causes.

FAQ for COVID-19 and Children: CDC updated Frequently Asked Questions and Answers: Coronavirus Disease-2019 (COVID-19) and Children. The questions discuss steps to protect children from the COVID-19 pandemic and multisystem inflammatory syndrome (MIS-C).

People Who Need Extra Precautions: CDC updated their information for People Who Need Extra Precautions and are at higher risk for severe illness. The webpage includes populations that are at higher risk for severe illness as well as other populations including individuals experiencing dementia, disabilities, pregnancy, homelessness, etc.

Rural Health and COVID-19: ASPR released a document on Rural Health and COVID-19. This ASPR TRACIE quick sheet, along with the ASPR TRACIE Rural Health and COVID-19 considerations resource identifies challenges faced by rural areas specific to COVID-19. The challenges are grouped into two main categories: those specific to healthcare facilities, and those related to at-risk populations who reside in rural areas. Considerations for meeting each challenge are also provided.

Information for Newly Resettled Refugee Populations: CDC released new information for Newly Resettled Refugee Populations. Refugees to the United States, especially those who are recently resettled, may be in living or working conditions that put them at higher risk of getting COVID-19. Some refugees have limited access to health care, as well as certain underlying medical conditions that may also put them at higher risk of more severe illness from COVID-19, compared to the rest of the U.S. population. The webpage includes information on what can be

done for refugee populations during COVID-19 outbreak and why refugees may be at higher risk during the outbreak.

Information for Agriculture Workers and Employers: CDC updated their guidance for Agriculture Workers and Employers. This guidance provides a template of action to protect agriculture workers from coronavirus disease 2019 (COVID-19). Agricultural employers can adapt these recommendations to protect workers at their particular work sites or in specific work operations.

Improving Food Safety in the Future: The agency issued a new FDA Voices, titled Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety, and bylined by Stephen M. Hahn, M.D., Commissioner of Food and Drugs, and Frank Yiannas, Deputy Commissioner for Food Policy and Response. In March, the FDA was a few days away from announcing the release of the New Era of Smarter Food Safety Blueprint when the FDA's focus turned to the COVID-19 pandemic. Plans for the New Era initiative were rightfully put on hold in order to prioritize the agency's COVID-19 response. The FDA will release the blueprint in the coming weeks, outlining plans over the next decade to create a more digital, traceable, and safer food system.

Pet Owners and COVID-19: CDC updated their information for pet owners. A small number of pets worldwide, including cats and dogs, have been reported to be infected with the virus that causes COVID-19, mostly after close contact with people with COVID-19. Infected pets might get sick or they might not have any symptoms. Of the pets that have gotten sick, most only had mild illness and fully recovered.

CMS Guidance

Updates on Innovation Models: CMS is providing new flexibilities and adjustments to current and future CMMI models to address the emergency. CMS also released a chart that outlines the models and the new changes. The table specifically focuses on model adjustments related to financial methodologies, quality reporting, and model timelines.

Testing for Uninsured Individuals: CMS released new guidance to states supporting implementation of the Optional COVID-19 Testing (XXIII) Group established by the Families First Coronavirus Response Act (FFCRA) for uninsured individuals for COVID-19 testing and testing-related services. This guidance identifies the different requirements associated with implementing the new group (including eligibility and enrollment, claiming, and data reporting), and provides guidance on strategies that states may employ to meet these requirements. It also describes flexibilities available to help states streamline implementation of the new group. States can also refer to Section B of the FFCRA and Coronavirus Aid, Relief, and Economic Security (CARES) Act Frequently Asked Questions (FAQs) posted April 13, 2020 for more detailed information on the eligibility requirements, benefits, and Federal Medical Assistance Percentage available for coverage under the optional COVID-19 testing group.

Medicare Fee-for-Service Billing: CMS updated their FAQ document on COVID-19 Medicare Fee-for-Service Billing. The FAQs cover a range of topics on payment, treatment and for various settings.

Research Updates

Study Results Among U.S. Air Force Basic Military Trainees: CDC released an MMWR on COVID-19 Monitoring and Response Among U.S. Air Force Basic Military Trainees. This was a study conducted in Texas from March to April of 2020 to study the transmission of COVID-19 in congregate living settings. Nonpharmaceutical interventions (NPI) introduced among 10,579 basic trainees at Joint Base San Antonio-Lackland limited COVID-19 incidence to five cases (47 per 100,000 persons), three of which were in persons who were contacts of the first patient. Despite documented outbreaks of COVID-19 in congregate settings, implementation of non-pharmaceutical interventions, including screening, testing, administrative measures, quarantine, isolation, and source control, can limit transmission of symptomatic COVID-19 and ensure continuity of critical activities.