HHS COVID-19 April 7, 2020 Update

CMS Updates:

Clinician Letter: CMS posted a letter to clinicians that outlines a summary of actions CMS has taken to ensure clinicians have maximum flexibility to reduce unnecessary barriers to providing patient care during the unprecedented outbreak of COVID-19. The summary includes information about telehealth and virtual visits, accelerated and advanced payments, and recent waiver information.

Recommendations on Non-Essential Medical Services: CMS recently updated recommendations to postpone non-essential surgeries and other procedures to conserve critical healthcare resources and limit exposure of patients and staff to COVID-19. Developed in collaboration with medical societies and associations, the recommendations outline a tiered approach for state and local officials, clinicians, and delivery systems to consider in prioritizing services and care to those who require emergent or urgent attention to save a life, manage severe disease, or avoid further harms from an underlying condition.

Increased Waiver Flexibility: CMS has approved Medicaid Disaster Amendments that bring disaster relief to Arizona, Alabama, and Minnesota to ensure that states have the tools they need to combat COVID-19 through a wide variety of state plan flexibilities. CMS also authorized amendments to ensure emergency flexibilities in programs that care for the elderly and people with disabilities, including most recently in Arizona, North Carolina, and South Dakota. All told, CMS has approved 49 emergency waivers, which now includes Michigan, Maine, Nevada, and the U.S. Virgin Islands, 21 State Amendments, and 3 Medicaid Disaster Amendments in record time. All of the emergency waiver actions can be found on CMS Federal Disaster Resources webpage.

2021 Medicare Advantage and Part D Rates: Yesterday CMS posted their 2021 Medicare Advantage and Part D Rates with a 1.08% increase in the effective growth rate between the Advance Notice and Final Rate Announcement. CMS remains committed to implementing the policies that matter most for ensuring continuous and predictable payments across the health care system and ensuring care can be provided where it is needed. While the Rate Announcement does not catalog CMS' actions related to the COVID-19 outbreak, CMS has created an overview of actions related to the outbreak for MA organizations, PACE organizations, and Part D sponsors.

Testing and Treatment

Purchase of Point in Care Testing: The Federal government announced that it is purchasing the ID NOW COVID-19 rapid point-of-care test, developed by Abbott Diagnostics Scarborough Inc., for state, territorial and tribal public health labs. The ID NOW COVID-19 test is performed on the ID NOW device. This test allows for medical diagnostic testing at the time and place of patient care, provides COVID-19 results in under 13 minutes and expands the capacity for coronavirus testing. HHS is providing these tests and devices to public health labs (PHLs) in every state and territory, and Washington, D.C. To ensure that remote and rural populations are also being reached, the Indian Health Service will receive tests and devices to distribute to tribal PHLs.

Hydroxychloroquine Tablets: The FDA approved an Abbreviated New Drug Application (ANDA) for Hydroxychloroquine Sulfate Tablets USP, 200 mg. for the treatment of: (1) Uncomplicated malaria due to P. falciparum, P. malariae, P. ovale, and P. vivax. (2) Chronic discoid lupus erythematosus and systemic lupus erythematosus in adults and (3) Treatment of acute and chronic rheumatoid arthritis in adults. Side effects of hydroxychloroquine include irreversible retinal damage, cardiac effects (including cardiomyopathy and QT prolongation), worsening of psoriasis and porphyria, proximal myopathy and neuropathy, neuropsychiatric events, and hypoglycemia. The FDA recently posted information regarding shortages of hydroxychloroquine and chloroquine to its drug shortages webpage due to a significant surge in demand. The agency is working with manufacturers to assess their supplies and is actively evaluating market demand for patients dependent on hydroxychloroquine and chloroquine for treatment of malaria, lupus and rheumatoid arthritis.

PPE and **Supplies**

Updated PPE Burn Rate Calculator: CDC updated their Burn Rate Calculator that is a spreadsheet-based model that will help healthcare facilities plan and optimize the use of PPE for response to coronavirus disease 2019 (COVID-19). Non-healthcare facilities such as correctional facilities may also find this tool useful.

Tracking and Monitoring Cases: The Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) is supporting the nation's COVID-19 response by introducing a new COVID-19 Patient Impact and Hospital Capacity Module within NHSN's Patient Safety Component. The Module enables hospitals to report daily counts of patients with suspected and confirmed COVID-19 diagnoses and current use and availability of hospital beds and mechanical ventilators. NHSN, in turn, will enable state and local health departments to gain immediate access to the COVID-19 data for hospitals in their jurisdictions.

Expanding Availability of Electronic Thermometers: The FDA issued guidance on clinical electronic thermometers that immediately went into effect. Fever is a common symptom of COVID-19 and clinical electronic thermometers are an important screening and diagnostic tool to assist in the identification of those individuals who may be infected with COVID-19. The policy set forth in the guidance may help expand the availability of clinical electronic thermometers to address this public health emergency.

Expanding Availability of Remote Ophthalmic Devices: the FDA issued a guidance for remote ophthalmic assessment and monitoring devices. These devices include visual acuity charts, visual field devices, general use ophthalmic cameras, and tonometers. The guidance will help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID-19 during this pandemic.

Availability of Infusion Pumps: The FDA issued guidance on infusion pumps and accessories that immediately went into effect. The guidance aims to help ensure the availability of infusion pumps and accessories for patients who require continuous infusion of medications, nutrition, and other fluids and help foster technologies, such as remote capabilities, that maintain a safer physical distance between the health care provider and the patient.

Expanding Availability of Cardiopulmonary Bypass Devices The FDA issued an updated policy to help expand the availability of cardiopulmonary bypass devices used in extracorporeal membrane oxygenation (ECMO) therapy to address this public health emergency.

Conservation Strategies for Medical Gloves: This Letter to Health Care Providers refers specifically to potential shortages relating to surgeons' gloves and patient examination gloves. The following conservation strategies are recommended for use by health care organizations and personnel and are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine procedures during the COVID-19 pandemic.

3-D Printing of Medical Supplies: FDA released an FAQ document for entities who 3D print devices, accessories, components, and/or parts during the COVID-19 emergency. The FAQs address which PPE supplies can be made via 3-D printing, recommendations and guidance from the FDA on the uses for 3-D printed PPE and other resources.

EPA to Donate PPE: The Environmental Protection Agency identified approximately 225,000 pieces of PPE that they will donate to state and local responders fighting COVID-19 across the country.

ASPR Resources for Supply Chain, Fatality Management, and Emergency Departments: ASPR has a site where resources can be uploaded to include plans, tools, templates, and other immediately implementable resources to help with COVID-19 preparedness, response, recovery, and mitigation efforts. The resources are for peers to share COVID-19 best or promising practices, plans, tools, or templates on fatality management, emergency departments, and supply chain.

Information for Specific Populations and Facilities

What Errands are Essential? CDC released information on the essential errands related to grocery shopping, take-out, banking, getting gas, and doctor visits. As communities across the United States take steps to slow the spread of COVID-19 by limiting close contact, people are facing new challenges and questions about how to meet basic household needs, such as buying groceries and medicine, and completing banking activities. The information provides advice about how to meet these household needs in a safe and healthy manner.

Additional Information on Social Distancing, Quarantine, and Isolation: CDC updated their information on Social Distancing, Quarantine, and Isolation. The information defines each term and provides guidance for individuals in case they feel sick.

Report on COVID-19 in Children: CDC published their first report that looks at COVID-19 Illness in Children in the United States in the MMWR. Topline findings include that while some children with COVID-19 may have mild illness and may not show symptoms, they can still spread the disease to others. The limited data suggest that young infants (<1 year of age) may be at higher risk of severe illness with COVID-19 compared with older children, but more information is needed to understand factors contributing to severe outcomes. The report also indicates that children with underlying health conditions are more likely to be hospitalized. Though children with COVID-19 infection may have mild disease, they can still spread COVID-19. It's important that people of all ages follow recommendations from CDC and state and local public health authorities to help prevent the spread of COVID-19.

Guidance for Healthcare Facilities Facing Staffing Shortages: CDC released information on Strategies to Mitigate Healthcare Personnel Staffing Shortages with recommendations for contingency and crisis capacity recommendations for consideration.

Protecting Healthcare Workers Psychological Health and Wellbeing: The resilience of our Nation's healthcare system depends on our healthcare workforce's ability to report for duty. Critical supplies, equipment, and surge capacity rely on dedicated, trained health professionals and support staff to provide care. This document provides recommendations to help healthcare facilities protect their workers' psychological health and well-being. The recommendations are categorized under tips to prepare the workforce before the surge takes place and supporting them effectively during the surge.

Updated Information on Management of Persons with Confirmed COVID-19: CDC updated their Interim Clinical Guidance for Management of Patients with Confirmed COVID-19 to include additional information on asymptomatic and pre-symptomatic patients, reinfection, non-steroidal drugs, possibility of infection with other viruses, additional laboratory and imaging findings, updated information from WHO and new resources on therapeutic options for patients with COVID-19.

Information for Pharmacy Staff: CDC released information on Considerations for Pharmacies during the COVID-19 Pandemic which advises pharmacy staff on strategies to minimize their risk of exposure to the virus and how to reduce the risk for customers during COVID-19.

Updated Information for Alternative Care Sites: CDC updated their Infection Control and Prevention in Alternative Care Sites guidance to align with the level of care categories to include general (non-acute) and acute care.

Guidance for Water Systems in Buildings: CDC released 8 steps that building managers should take to ensure the safety of their building water system and devices after a prolonged shutdown.

Faith-Based Organizations Eligible to Receive SBA Loans: The Small Business

Administration has clarified that faith-based organizations and congregations are eligible to receive loans through the Paycheck Protection Program and the Economic Injury Disaster Loans loan programs for COVID recovery, regardless of whether they provide secular social services, and without restrictions based on their religious identity or activities, to the extent they meet the eligibility criteria outlined in the CARES Act. The SBA released an FAQ document that further outlines the details of the program and how faith-based organizations can qualify for and apply for the loans.

World Health Day: Secretary Azar released the following statement on World Health Day: The United States has worked to focus global health priorities and the efforts of the World Health Organization on infectious outbreaks that can cross borders. Now, we face a pandemic that has spread to almost every country on earth, costing lives, disrupting societies, and stalling economies. On World Health Day, we rededicate ourselves, as an international community and as individual nations, to fighting this pandemic with science-based public health policies. Working together, we will defeat this invisible enemy and our countries will emerge from this crisis stronger for it—knowing that preparing for such crises must always be one of our top global health priorities.