Wynne Health Group

Memorandum

April 7, 2020

CATALOGUE OF HEALTH AGENCY GUIDANCE AND GOVERNMENT RESPONSE TO COVID-19

As the novel coronavirus outbreak (COVID-19) has taken hold, U.S. government agencies have ramped up the rapid release of fact sheets and guidance documents on a near hourly basis. To help navigate the outpouring of information, this newly updated catalogue is intended to encapsulate and organize the relevant guidance for health care providers, insurers, state governments, public health agencies, and other stakeholders, as well as capture the status of major actions by the White House and Congress. Follow the hyperlinks to jump to each section.

Updated April 7, 2020

CENTERS FOR MEDICARE & MEDICAID SERVICES

Section 1135 Waivers and other Emergency Flexibilities

- **April 7:** CMS approved Section 1135 waiver requests for Maine, the U.S. Virgin Islands, Nevada, Michigan, and the District of Columbia, bringing the total number to 49.
- **April 2**: CMS approved Section 1135 waiver requests for Georgia, Alaska, Arkansas, and Nebraska, bringing the total number to 44.
- **March 31:** CMS approved an additional two state Medicaid waiver requests under Section 1135 – South Carolina and Tennessee – bringing the total number of approved Section 1135 waivers to forty.
- **March 30:** CMS announced a landmark array of new waivers and flexibilities for Medicare providers to address the surge in COVID-19 cases. (WHG client summary here).
- **March 30:** CMS approved 1135 waivers for Montana, Texas, Vermont, and West Virginia, bringing the total number approved to 38. All waivers are available here.
- **March 27**: CMS announced it approved a total of 34 state applications for 1135 waiver authority to respond to the COVID-19 outbreak. (WHG client summary).
- **March 26:** CMS approved 1135 waivers for the following states: New York; Colorado; Hawaii; Idaho; Massachusetts; and Maryland.

- **March 25:** CMS approved 1135 waivers for the following states: Kentucky; Rhode Island; Iowa; Indiana; Kansas; Missouri; and Oregon.

- **March 23:** CMS announced the approval of 1135 waiver requests from 11 states, including: Alabama, Arizona, California, Illinois, Louisiana, Mississippi, New Hampshire, New Jersey, New Mexico, North Carolina, and Virginia. Additional Section 1135 approval letters will be posted here as they are issued. (WHG client summary).

- **March 22:** CMS released new checklists and tools designed to support state Medicaid and CHIP programs in pursuing the various regulatory flexibilities that became available when President Trump declared COVID-19 a national emergency. (WHG client summary).

- **March 19:** CMS approved an 1135 Medicaid waiver request for the state of Washington.

- **March 17:** CMS approved a Section 1135 waiver request for the state of Florida in response to the COVID-19 national emergency, which will allow the state to waive prior authorization requirements, streamline provider enrollment processes, allow care to be provided in alternative settings, and more. Additional Section 1135 approval letters will be posted here as they are issued.

- **March 13:** CMS released a fact sheet (press release) outlining provider flexibilities in response to the national emergency declaration, including Section 1135 waivers of certain Medicare, Medicaid, and CHIP requirements and how they apply to different settings of care. (WHG client summary). The transcript and audio recording from a National Stakeholder Call on these flexibilities is available here.

Infection Control and Prevention

- **April 7:** CMS issued recommendations regarding non-emergent and elective medical services. CMS provides a tiered framework to prioritize services and care to those who require urgent or emergent attention, while underlining that decisions remain the responsibility of local healthcare delivery systems.

- **April 2:** CMS released new guidance to state and local governments and long-term care facilities (i.e., nursing homes) to aid in limiting the spread of COVID-19 (WHG client summary).

- **March 17**: CMS issued COVID-19 guidance to all Programs of All-Inclusive Care for the Elderly (**PACE) Organizations** (POs). PACE is a Medicare and Medicaid program that helps people meet their healthcare needs in the community instead of going to a nursing home or other care facility.

- **March 13**: CMS released an updated memorandum based on recommendations from the CDC directing **nursing homes** to significantly restrict visitors and nonessential personnel, as well as restrict communal activities inside nursing homes.

- **March 10:** CMS issued memoranda to **dialysis facilities** (here) and **home health** providers (here) on screening and containment strategies for patients, visitors, and staff. (WHG client summary).

- **March 9:** CMS published guidance to hospitals with **emergency departments** (EDs) on patient screening, treatment and transfer requirements to prevent the spread of infectious disease and illness, including COVID-19.

- **March 9:** CMS released guidance on the screening, treatment and transfer procedures healthcare workers must follow when interacting with patients to prevent the spread of COVID-19 in a **hospice** setting. CMS also issued guidance specific to nursing homes to help control and prevent the spread of the virus (WHG client summary).

- **March 4:** CMS announced new actions the agency is taking to limit the spread of COVID-19, and released a series of memoranda for U.S. health care facilities and **nursing homes** on how they should respond to and contain the threat of the outbreak. (WHG client summary).

Personal Protective Equipment (PPE)

- **March 18:** CMS issued tiered recommendations (press release) for health care providers on limiting non-essential adult elective surgery and medical and surgical procedures, including all dental procedures. (WHG client summary).

- **March 10:** CMS issued guidance on the CDC's updated Personal Protective Equipment (PPE) recommendations for health care workers. (WHG client summary).

Telehealth & Provider Enrollment

- **April 6:** CMS released a video answering common questions about the recent Medicare telehealth expansions.

- **April 3:** CMS released a memo to State Survey Agency Directors outlining new flexibilities that allow enrolled ambulatory surgical centers (ASCs) to temporarily enroll as hospitals and provide hospital services.

- **March 27:** CMS released another telehealth toolkit, this time for long-term care nursing homes. (WHG client summary).

- **March 22:** CMS released FAQs on Medicare Provider Enrollment Relief related to COVID-19 including the toll-free hotlines available to provide expedited enrollment and answer questions related to COVID-19 enrollment requirements.

- **March 20:** CMS released two toolkits – one for general practitioners (here) and one for providers treating end-stage renal disease (here) – collating key resources in answering telehealth-related questions. (WHG client summary).

- **March 17:** CMS released anticipated guidance on new Medicare telehealth flexibilities triggered by the national emergency declaration in response to the COVID-19 outbreak (press release; accompanying FAQs; accompanying document). Effectuated per authorities granted under the coronavirus emergency supplemental bill. (WHG client summary).

- **March 9:** CMS issued a press release highlighting the telehealth benefits in the agency's Medicare program for use by patients and providers.

Coding and Reimbursement

- **April 7**: CMS released a Dear Clinician Letter outlining policies related to accelerated and advanced payments, testing and claims reporting for COVID-19, Medicare telehealth visits, expanded options for telehealth services, workforce flexibilities, and the CMS quality payment program.

- **March 28:** CMS announced it is expanding advanced and accelerated payments for providers and suppliers to support response efforts to the COVID-19 outbreak (fact sheet). (WHG client summary).

- **March 5:** CMS announced it has issued a second Healthcare Common Procedure Coding System (HCPCS) code that diagnostic laboratories can use to bill for certain COVID-19 tests. (WHG client summary).

Benefits and Coverage

- **March 24:** CMS announced qualified health plans (QHPs) would be permitted to extend payment deadlines and delay the beginning of applicable grace periods for enrollees. (WHG client summary).

- **March 18:** CMS issued FAQs to clarify coverage for the diagnosis and treatment of COVID-19 by catastrophic health plans.

- **March 13:** CMS released a fact sheet to assist Medicare providers with information related to the price of CDC tests and non-CDC tests for COVID-19. (WHG client summary).

- **March 12:** CMS issued Frequently Asked Questions (FAQs) to ensure individuals, issuers and states have clear information on coverage benefits for COVID-19 based on the ACA's essential health benefits (EHBs).

- **March 10:** CMS issued guidance to help Medicare Advantage and Part D plans respond to the coronavirus (WHG client summary).

Medicaid & CHIP

- **April 2:** CMS updated its set of FAQs providing additional information on coronavirus response strategies for Medicaid and CHIP agencies (WHG client summary). The most recently updated version of this document is available here.

- **March 24:** CMS released set of FAQs designed to give state Medicaid programs implementation guidance on the 6.2 percent increase in the Federal Medical Assistance Percentage (FMAP) for each state and territory, which was made possible under Section 6008 of the Families First Coronavirus Response Act. (WHG client summary).

- **March 17:** CMS released sample state plan language in a document intended to assist states in understanding policy options for paying Medicaid providers that use **telehealth** technology to deliver services in combating the COVID-19 pandemic.

- **March 6:** CMS released a fact sheet outlining coverage and benefits related to COVID-19 in Medicaid CHIP.

For State Survey Agencies, Accrediting Organizations

- **March 23:** CMS released a fact sheet outlining a targeted, streamlined survey process for healthcare facility inspections, further refined from guidance provided earlier this month. The agency issued the guidance based in part on findings of a recent inspection of the Life Care Center **nursing home** in Kirkland, Washington – the epicenter of the COVID-19 outbreak in that state. (WHG client summary).

- **March 4:** CMS issued a memo to State Survey Agencies and Accrediting Organizations indicating that, effective immediately, all non-emergency inspection activities are suspended so that inspectors can turn their focus to the most serious health and safety threats, including abuse and COVID-19 and other infectious disease control. (WHG client summary).

FEDERAL COMMUNICATIONS COMMISSION

Telehealth

- **April 2:** The FCC announced it voted to adopt the $200 million COVID-19 Telehealth Program (details).

- **March 30:** The Chairman of the Federal Communications Commission (FCC) announced a new plan dedicating $200 million to support health care facilities standing up telehealth programs in response to the COVID-19 pandemic. (WHG client summary).

FOOD & DRUG ADMINISTRATION

Blood Supply

- **April 2:** FDA issued guidance to address the urgent need for blood during the COVID-19 pandemic. This guidance revises previous recommendations regarding blood donor eligibility in order to expand access to critically needed bloody supply (WHG client summary).

Medical Devices

- **March 24:** FDA issued a Letter to the Industry detailing steps taken by Center for Devices and Radiological Health (CDRH) to address the impact of COVID-19 on the day-to-day operations, while prioritizing efforts to respond to the national emergency (WHG client summary).

- **March 20:** FDA issued guidance to expand the use of devices to remotely monitor patient's vital signs (WHG client summary).

Treatments and Vaccines

- **April 1:** FDA announced that the FDA-ARGOS-CoV-2 Reference Grade Sequence Data is now available. This will help test developers and vaccine developers expedite the development of countermeasures, identify new or more stable targets for future tests, and support development of synthetic reference material.

- **March 31:** FDA announced the Coronavirus Treatment Acceleration Program (CTAP), a new program intended to expedite the development of safe and effective life-saving treatments (WHG client summary)

- **March 28:** FDA issued Emergency Use Authorization (EUA) to allow chloroquine phosphate and hydroxychloroquine phosphate products to be distributed and used for patients with COVID-19 (WHG client summary).

- **March 24:** FDA is facilitating access to COVID-19 convalescent plasma for use in patients with serious of immediately-life threatening COVID-19 infections through single patient emergency Investigational New Drug Applications (eINDs).

- **March 18:** FDA issued guidance on conducting clinical trials during the COVID-19 outbreak, including considerations for protocol modifications (WHG client summary).

- **March 9:** FDA and FTC warned seven companies selling products claiming to treat or prevent COVID-19. FDA notes these products are unapproved and pose a significant risk to patient health.

Personal Protective Equipment (PPE)

- **March 27:** FDA issued two Emergency Use Authorizations (EUAs) to increase the supply of ventilators and respirators. The first EUA allows for the emergency use in health care settings of certain ventilators, ventilator tubing connectors, and ventilator accessories, while the second EUA was issued for certain imported non-National Institute for Occupational Safety and Health (NIOSH) approved respirators (WHG client summary)

- **March 26:** FDA issued guidance to expand the availability of general use face masks for the general public and particulate filtering facepiece respirators, including N95 facemasks, for health care professionals. (WHG client summary)

- **March 24:** FDA provided instructions to manufacturers to import personal protective equipment (PPE) and other devices (WHG client summary)

- **March 22:** FDA issued guidance to expand the manufacturing and availability of ventilators and other respiratory devices, such as CPAP machines (WHG client summary).

- **March 20:** FDA issued two temporary policies to increase the production of alcohol-based hand sanitizer. Under the guidance manufacturing firms, pharmacies, and outsourcing facilities may produce or compound handrub products (WHG client summary).

- **March 11:** FDA issued a letter to health care providers on recommendations for mask and gown conservation (WHG client summary).

- **March 2:** FDA and CDC took action to allow certain National Institute for Occupational Safety and Health (NIOSH) approved respirators not currently regulated by the FDA to be used in the health care setting by health care personnel.

Diagnostic Testing

- **April 6:** To date, the FDA has issued 36 Emergency Use Authorization (EUA) diagnostic tests. This includes 29 in-vitro diagnostic test kits and 5 high complexity molecular-based tests

- **April 2:** FDA issued the first Emergency Use Authorization (EUA) for a test that analyses blood antibodies to determine if an individual has been exposed to COVID-19. This will allow people who have recovered from the virus to be identified.

- **March 31:** FDA issued an EUA for SARS-CoV-2 PCR test, a serological testing kit which can detect a positive or negative test result in two minutes.

- **March 26:** To date, the FDA has issued 17 EUAs for diagnostic tests, including AvellinoCoV2, which is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2. The FDA has also kept it COVID-19 Diagnostic FAQ up to date.

- **March 21:** FDA issued the first EUA for a point-of-care COVID-19 diagnostic for the Cepheid Xpert Xpress SARS-CoV-2 test.

- **March 20:** FDA warns consumers about unauthorized fraudulent COVID-19 test kits.

- **March 16**: FDA announced new state flexibility to authorize diagnostic test and updated existing policy to include commercial manufacturers (WHG client summary).

- **March 16**: FDA issued two additional Emergency Use Authorization (EUA) diagnostics to Hologic for its Panther Fusion SARS-COV-2 Assay and to Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.

- **March 13:** FDA issued the fourth COVID-19 Emergency Use Authorization (EUA) diagnostic to Thermo Fisher for its TaqPath COVID-19 Combo kit.

- **March 12:** FDA issued new flexibilities to the New York State Department of Health to address the COVID-19 outbreak and issued the third Emergency Use Authorization diagnostic. (WHG client summary).

- **February 29:** FDA issued Emergency Use Authorizations (EUAs) to two public health labs in New York for diagnostics to test COVID-19.

- **February 29:** FDA issued guidance to provide a policy for COVID-19 diagnostic tests developed and used in clinical laboratories under the Clinical Laboratory Improvements Amendments (CLIA) in order to expedite testing capacity (WHG client summary).

Food and Drug Safety and Supply Chain

- **March 27:** FDA issued guidance on the importance of notifying the agency of any discontinuance or interruption of drug and biological product manufacturing.

- **March 27:** FDA issued a letter to stakeholders detailing the danger of taking chloroquine phosphate products intended to treat disease in aquarium fish.

- **March 26:** FDA issued guidance on a temporary policy regarding nutrition labeling of certain packaged food during COVID-19 public health emergency.

- **March 17:** FDA issued a temporary policy for FDA Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements during the COVID-19 emergency.

CENTERS FOR DISEASE CONTROL & PREVENTION

Funding Opportunities

- **April 6:** CDC will award $186 million in supplemental funding to states and local jurisdictions to support their public health infrastructure. Specifically, $160 million will be provided through the Public Health Crisis Response Cooperative Agreement (CoAg) and $26.3 million will be provided through the Emerging Infections Program (EIP). In addition, $80 million in supplemental funding is underway for tribal governments and organizations. The funding was made available through the Phase I COVID-19 package. See here for supplemental funding data by jurisdiction.

- **April 2:** CDC issued a funding opportunity titled, "COVID-19 Response Supplement Part B: Tribal Public Health Capacity-Building and Quality Improvement Umbrella Cooperative Agreement" (CDC-RFA-OT18-18030203SUPP20). The application deadline is April 8, 2020.

- **April 1:** CDC issued a funding opportunity titled, "Supporting Tribal Public Health Capacity in Coronavirus Preparedness and Response" (CDC-RFA-OT20-2004). The application deadline is May 31, 2020.

- **March 31:** CDC released Frequently Asked Questions: COVID-19 Crisis Response Cooperative Agreement – Components A and B Supplemental Funding Interim Guidance.

- **March 15:** CDC activated the Cooperative Agreement for Emergency Response: Public Health Crisis Response (CDC-RFA-TP18-1802) and issued interim guidance regarding Components A and B Supplemental Funding.

Treatment

- **March 23:** CDC released new information on therapeutic options for the treatment of patients with COVID-19 (WHG client summary).

For Providers

- **April 3:** CDC launched COVIDView – a weekly surveillance weekly summary of U.S. COVID-19 activity. It includes information related to COVID-19 outpatient visits, emergency department visits, hospitalizations and deaths, as well as laboratory data. The report will be updated each Friday.

- **April 2:** CDC released contingency and crisis capacity strategies about decontamination and reuse of filtering facepiece respirators (FFRs) (WHG client summary).

- **March 31:** CDC released a Morbidity and Mortality Weekly Report (MMWR) titled, "Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019 – United States, February 12-March 28, 2020."

- **March 25:** CDC updated Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for COVID-19.

- **March 25:** CDC released preparedness checklists for hospitals and healthcare professionals preparing for patients with suspected or confirmed COVID-19.

- **March 24:** CDC issued Interim Additional Guidance for Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities.

- **March 18:** CDC released *Prepare to Care for COVID-19* - a new resource containing clinical tools for health care providers caring for patients with COVID-19. The resource includes steps clinicians can take to prepare their clinic to protect patients and health care workers from COVID-19 (before patients arrive, when patients arrive, and after patients are assessed); outdoor and indoor signs; and a patient handout with tips for home care.

- **March 18:** CDC released a Morbidity and Mortality Weekly Report (MMWR) titled, "Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) - United States, February 12-March 16, 2020.

- **March 17:** CDC updated its FAQs for healthcare professionals on COVID-19 regarding whether pregnant health care personnel are at increased risk if they care for patients with COVID-19. CDC recommends pregnant healthcare personnel to follow risk assessment and infection control guidelines for personnel exposed to patients with suspected or confirmed COVID-19.

- **March 11:** HHS announced that the CDC is moving forward with awarding more than $560 million of the $8.3 billion in supplemental spending passed by Congress. The funding will be provided to states, localities, territories, and tribes, to assist with the coronavirus response.

For the Public

- **April 3:** CDC released new recommendations for individuals to wear cloth face coverings in public settings where other social distancing measures are difficult to maintain.

- **March 20:** CDC will provide $80 million in funding to tribes, tribal organizations, and Urban Indian Organizations for resources to support the 2019 novel coronavirus (COVID-19) response. (WHG client summary).

- **March 11:** CDC Released mitigation strategies to help stop the spread of the coronavirus (WHG client summary).

- **February 20:** CDC issued an Order aimed at controlling the introduction, transmission, and spread of communicable diseases into the United States, such as COVID-19. (WHG client summary).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

- **April 6:** HHS announced that the Centers for Disease Control and Prevention (CDC) is to provide $186 million in funding for state and local government response to COVID-19. CDC plans on using the supplemental funding to support "hot zones" with the highest number of reported cases and increase funding for the Emerging Infections Program to enhance surveillance capabilities.

- **April 6:** HHS announced that it is purchasing the ID NOW COVID-19 rapid point-of-care test, developed by Abbott Diagnostics Scarborough Inc., for use in state, territorial, and tribal public health labs. The test allows diagnostic testing at the time and place of patient care and provides results in under 13 minutes.

- **March 31:** The HHS Assistant Secretary for Health and the U.S. Surgeon General issued an open letter to the health care community describing the need to carefully manage the supply of mechanical ventilators. The letter also suggests a possible "crisis standard-of-care strategy" of using one ventilator for two patients.

OFFICE FOR CIVIL RIGHTS

- **April 2:** OCR announced it will extend privileges to disclose private health information (PHI) that have been afforded to covered entities during the COVID-19 emergency to their business associates as well. This will enable both covered entities and their business associates to share PHI for health oversight activates without risk of a HIPAA penalty.

- **March 30:** OCR issued a bulletin reminding providers that current anti-discrimination rules and new HIPAA flexibilities apply to the COVID-19 response. The new HIPAA flexibilities available to covered entities, include: enforcement discretion to allow providers to provide telehealth communications remotely; disclosure of protected health information without prior HIPAA authorization; and the ability for providers to share information with the CDC, family members of patients, and others (WHG client summary).

- **March 20:** OCR issued guidance on telehealth remote communications following its Notification of Enforcement Discretion during the COVID-19 nationwide public health emergency.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

- **March 30:** BARDA announced it will support vaccines in development by Janssen (non-clinical studies and a Phase 1 clinical trial) as well as Moderna and the National Institute of Allergy and Infectious Diseases (Phase 2 and 3 clinical trials) (WHG client summary).

- **March 24:** ASPR announced it will provide $100 million in aid to the National Special Pathogen Treatment System, as directed by the Coronavirus Preparedness and Response Supplemental Appropriations Act, to assist healthcare systems with preparing for a surge in COVID-19 patients (WHG client summary).

- **March 21:** BARDA announced will provide support for a U.S. Phase 2/3 clinical trial to evaluate Kevzara – developed under a collaboration between Regeneron and Sanofi for the treatment of rheumatoid arthritis – as a potential treatment for severely ill COVID-19 patients.

- **March 18**: ASPR announced a public-private partnership to create a high-speed, high-volume, emergency drug packaging solution using low-cost prefilled syringes (WHG client summary).

- **March 18:** BARDA announced it would help fund development of a fourth COVID-19 diagnostic test (WHG client summary).

- **March 13**: The Biomedical Advanced Research and Development Authority (BARDA) within ASPR provided advanced support to rapidly develop two diagnostic tests for COVID-19, Simplexa COVID-19 Direct Assay and QIAstat-Dx RPS2 test.

- **March 9:** ASPR announced it will provide advanced development support to a diagnostic test for COVID-19 that can be used to process up to 1,000 tests in 24 hours, which is being developed by Hologic, Inc. (WHG client summary).

- **March 4:** ASPR announced its intent to purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile.

- **February 18:** ASPR announced collaboration with Janssen and Sanofi for the development of COVID-19 therapeutics and vaccines, respectively.

OFFICE OF THE INSPECTOR GENERAL

- **April 6:** OIG released the results of a "pulse survey" conducted with hospital administrators between March 23 and March 27. The survey was designed to provide decision makers with a national snapshot of hospitals' challenges and needs in responding to the COVID-19 pandemic.

- **April 3:** OIG released a statement explaining that it will not impose administrative sanctions under the Federal anti-kickback statute for actions covered under the blanket waiver issued by CMS. OIG notes that this applies to conduct occurring on or after April 3, 2020 and will remain in effect as long as the blanket waiver is in place.

- **April 3:** OIG stated that it is accepting questions regarding the application of its administrative enforcement authorities, including the Federal anti-kickback statute and civil monetary penalty provision prohibiting inducements to beneficiaries. In addition to answering questions, OIG continues to offer advisory opinions (legally binding opinions about the application of fraud and abuse authorities on an existing or proposed business arrangement) and update its FAQs.

- **March 30:** OIG posted a message describing its efforts to minimize the burden on providers while rooting out bad actors during the COVID-19 pandemic.

- **March 17:** OIG released a statement indicating it will not subject physicians and other practitioners to administrative sanctions when a provider reduces or waives cost-sharing obligations that a beneficiary may owe for telehealth services if they are provided in a manner consistent with the applicable coverage and payment rules during the COVID-19 public health emergency.

NATIONAL INSTITUTES OF HEALTH

- **March 23:** NIH announced the launch of a website containing important educational resources for COVID-19 workers dealing with the spread of the virus.

- **March 17:** NIH, expressing concern for the health and safety of people involved in NIH research, issued guidance and information on flexibilities for NIH applicants and grantees.

- **March 16:** NIH announced the beginning of the first Phase I clinical trial for an investigational COVID-19 vaccine. The Seattle-based trial will enroll 45 healthy adult volunteers and will last approximately six weeks (WHG client summary).

- **Feb. 25:** NIH announced the beginning of a randomized, controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral remdesivir in hospitalized adults diagnosed with COVID-19 at the University of Nebraska Medical Center (UNMC) in Omaha.

U.S. DEPARTMENT OF AGRICULTURE (FOOD & NUTRITION SERVICE)

- **March 26:** USDA announced a host of new nationwide waivers of certain requirements under the SNAP, WIC, and Child Nutrition Programs to allow for flexible meal patterns and delivery methods during the pandemic, and to ease administrative burden. State guidance on such waivers is available here. (WHG client summary).

- **March 17:** USDA Secretary Perdue announced a collaboration with the Baylor Collaborative on Hunger and Poverty, McLane Global, PepsiCo, and others to deliver nearly 1,000,000 meals per week to students in a limited number of rural schools closed due to COVID-19. Eligibility details for schools is here.

- **March 10:** At a House Appropriations Subcommittee Hearing on the FY 2021 USDA Budget, Secretary Sonny Perdue discussed the flexibilities available to low-income school districts that may need to adjust their food service programs in the event of coronavirus-related school closures. (WHG client summary).

THE INTERNAL REVENUE SERVICE

- **March 31:** The Treasury Department and the IRS launched the Employee Retention Credit, a refundable tax credit of 50 percent up to $10,000 in wages paid by an eligible employer whose business has been financially impacted by COVID-19.

- **March 30:** The Treasury Department and the IRS announced that distribution of economic impact payments will begin in the next three weeks. The IRS also shared information regarding eligibility and logistics for receiving payment.

- **March 25:** The IRS revealed the People First Initiative, a series of taxpayer relief actions to help people facing financial stress as a result of COVID-19.

- **March 20:** The Treasury Department, IRS, and the Department of Labor announced that small and midsize employers can begin using two new refundable payroll tax credits created under the Families First Coronavirus Response Act. The tax credits will reimburse eligible employers, dollar-for-dollar, for the cost of providing COVID-19-related leave to their employees.

- **March 18:** The IRS announced that it is automatically extending federal income tax payment deadlines for individuals and corporations (regardless of the amount owed) to July 15, 2020. Formal guidance is available here.

- **March 11:** The IRS announced that high deductible health plans (HDHPs) are able to cover coronavirus costs without cost-sharing.

DEPARTMENT OF JUSTICE

- **April 4:** DOJ issued a letter noting it would not challenge a collaborative effort, developed and led by FEMA and HHS, for McKesson Corporation, Owens & Minor Inc., Cardinal Health Inc., Medline Industries Inc., and Henry Schein Inc. to fast-track and increase manufacturing, sourcing, and distribution of PPE and COVID-19-treatment-related medication.

- **April 2:** DOJ announced the distribution of hoarded personal protective equipment (PPE), including 192,000 N95 masks, 598,000 medical grade gloves, and 130,000 surgical masks. This PPE will be deployed to New York and New Jersey.

- **March 24:** The DOJ and the Federal Trade Commission issued a joint statement which outlines an expedited process for all COVID-19-related requests, and commits the agencies to addressing those which impact public health and safety within seven calendar days (WHG client summary).

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

- **March 18**: HUD Secretary Ben Carson, in consultation with the Trump Administration and the Coronavirus Task Force, authorized the Federal Housing Administration (FHA) to implement an

immediate foreclosure and eviction moratorium (press release) for single family homeowners with FHA-insured mortgages for the next 60 days.

FEDERAL EMERGENCY MANAGEMENT AGENCY

- **April 4:** FEMA announced it has obligated more than $44 million to the State of Iowa to purchase PPE and other supplies for its COVID-19 response.

- **April 2:** FEMA published a fact sheet outlining the requirements private non-profit (PNP) organizations must meet to be eligible to apply for funding through the Public (PA) Assistance Program.

- **March 31:** FEMA released a FAQ about non-congregate sheltering during the COVID-19 public health emergency.

- **March 31:** FEMA released a fact sheet detailing criteria that emergency medical care activities must meet to be eligible for funding through the Public Assistance (PA) Program.

- **March 30:** FEMA and HHS announced the creation of a Supply Chain Stabilization Task Force. This task force is taking a "whole-of-America approach" to address limited supply of critical protective and life-saving equipment such as PPE and ventilators. More information about the approach is available here.

- **March 29:** FEMA released information about how to secure 100 percent federal funding for use of the National Guard under Title 32.

- **March 27:** FEMA announced opportunities for the private sector to support the COVID-19 response, including selling and donating supplies, as well as ways for medical professionals to volunteer. More information about how to help is available here.

- **March 27:** FEMA sent a letter to state and local emergency managers asking them to immediately consider and implement seven steps in response to the COVID-19 pandemic. The agency noted that state and local government emergency mangers should not wait on PPE from the federal government and are encouraged to "take aggressive action now" and source their own (WHG client summary).

- **March 23:** FEMA signaled its intention to fund eligible emergency protective measures to respond to COVID-19 pursuant to Category B of the standing Public Assistance (PA) Program (WHG client summary).

ADMINISTRATION FOR COMMUNITY LIVING

- **March 24:** ACL announced it is distributing $250 million in grants, funded by the Families First Coronavirus Response Act, for nutrition services programs authorized by the Older Americans Act of 1965 (WHG client summary).

HEALTH RESOURCE SERVICES ADMINISTRATION

- **March 24:** HRSA announced that it was awarding 1,381 health centers across the country a collective $100 million in funding through the Coronavirus Preparedness and Response Supplemental Appropriations Act (WHG client summary).

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

- **April 1**: SAMHSA announced a funding opportunity for emergency grants to address mental and substance use disorders during COVID-19 (WHG client summary).

- **March 31:** SAMHSA updated is FAQ document on the provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency

- **March 22:** SAMHSA published a set of FAQs related to COVID-19 for grant recipients

- **March 20:** SAMHSA issued considerations for the care and treatment of mental and substance use disorders during the COVID-19 epidemic.

- **March 20:** SAMHSA issued considerations for outpatient mental and substance use disorder treatment settings.

- **March 19:** SAMHSA issued 42 CFR Part 2 guidance to ensure that substance use disorder treatment services are uninterrupted during this public health emergency.

- **March 18:** SAMHSA issued interim COVID-19 considerations for state psychiatric hospital

SMALL BUSINESS ADMINISTRATION

- **April 3**: The SBA issued an interim final rule providing additional guidance regarding the Paycheck Protection Program (WHG client summary).

- **April 2**: The SBA issued Economic Injury Disaster Loan (EIDL) declarations for each State and Territory in the U.S. (WHG client summary).

THE WHITE HOUSE

- **April 3:** During the COVID-19 task force briefing, the administration stated it will use a portion of the $100 billion from the CARES Act to cover providers' costs of caring for uninsured patients with COVID-19. The administration will prohibit providers from balance billing the uninsured for the cost of their care as a condition of receiving this funding. Providers will be reimbursed at Medicare rates.

- **April 2:** President Trump invoked the Defense Production Act to: (1) require General Electric Company; Hill-Rom Holdings, Inc.; Medtronic Public Limited Company; ResMed Inc.; Royal Philips N.V.; and Vyaire Medical, Inc. to prioritize the production of ventilators; and (2) require 3M to prioritize the production of N-95 respirators.

- **March 29:** President Donald Trump announced that the CDC was extending its social distancing guidelines until April 30. The president also announced that Humana and Cigna would waive all cost-sharing, co-pays, and deductibles for treatment related to COVID-19.

- **March 29:** Vice President Pence sent a letter to hospitals asking them to report data about both COVID-19 testing and hospital capacity on a daily basis. The administration intends to use the data to better understand COVID-19 disease patterns and to inform the development of policies for prevention and control (WHG client summary).

- **March 22:** President Trump issued a memorandum outlining federal support measures for states using the National Guard in response to the COVID-19 outbreak. (WHG client summary).

- **March 18:** President Trump signed the Families First Coronavirus Response Act (H.R. 6201) into law.

- **March 18**: President Trump delivered remarks indicating that the Administration will be invoking the Defense Production Act, "just in case," and deploying two military hospitals ships – one to New York and one to California – among other actions. This was followed by an Executive Order on Prioritizing and Allocating Health and Medical Resources.

- **March 16:** President Trump and the White House Coronavirus Task Force issued new guidelines to help protect Americans during the global Coronavirus outbreak, called 15 Days to Slow the Spread.

- **March 13:** President Trump officially classified the COVID-19 outbreak as a national emergency, under the Stafford Act.

- **March 11:** President Trump announced a travel ban to Europe during a primetime news briefing to the nation.

- **March 6:** President Trump signed into law H.R. 6074, the $8.3 billion emergency supplemental appropriation to address the coronavirus (COVID-19) outbreak. (WHG client summary).

- **March 3:** President Trump issued a proclamation restricting travel into the United States from non-citizens who were present in Iran during the 14-day preceding their attempted entry into the United States. (WHG client summary).

- **March 2:** White House and agency leaders spoke with the business community about COVID-19, how the government is responding, and what businesses are urged to do to limit exposure and spread. (WHG client summary).

CONGRESSIONAL RESPONSE

Legislation

- **April 4:** House Speaker Nancy Pelosi (D-A) sent a "Dear Colleague" letter to all members on next steps on CARES Act and "CARES 2." Speaker Pelosi is calling for additional funding and

resources for hospitals and community health centers. states and localities, and small businesses; more generous unemployment benefits; and additional direct payments for individuals.

- **March 27:** President Trump signed the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748) shortly after the House passed the package by a voice vote. The President also signed a Presidential Memorandum directing the Secretary of Health and Human (HHS) Services to invoke the Defense Production Act in order to require General Motors to prioritize the production of ventilators. (WHG client summary).

- **March 27:** The House Appropriations Committee released a fact sheet on funding streams, authorized under the Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748), to assist state and local governments, as well as nonprofits in responding to the COVID-19 pandemic.

- **March 25:** Senate released an updated version of the Coronavirus Aid, Relief, and Economic Security (CARES) Act – a package of bills intended to strengthen the federal government and health care system's response to COVID-19, as well as provide economic relief to individuals and businesses (WHG client summary).

- **March 23**: House Democrats introduced the Take Responsibility for Workers and Families Act – a package of proposals intended to bolster the federal government's response to COVID-19, as well as provide economic relief to individuals and businesses (including hospitals).

- **March 22:** On Sunday evening, March 22, 2020, the Senate rejected (47-47) a motion to proceed to Senate Majority Leader McConnell's updated $1.6 trillion COVID-19 economic stimulus package – the CARES Act. The bill text had been updated to include various Medicare, Medicaid and other key health care "extenders" and appropriations language; however, Democrats objected to its so-called "no-strings attached corporate slush fund" and inadequate funding for hospitals and individuals. (WHG client summary).

- **March 19:** Senate Majority Leader Mitch McConnell (R-KY) released the Coronavirus Aid, Relief, and Economic Security (CARES) Act – the "phase 3" coronavirus stimulus package. (WHG client summary).

- **March 18:** President Trump signed the Families First Coronavirus Response Act (H.R. 6201) into law.

- **March 18:** The Senate passed the Families First Coronavirus Response Act (H.R. 6201) by a vote of 90-8.

- **March 16:** The House approved by unanimous consent H.Res. 904 to make technical corrections to the Families First Coronavirus Response Act (H.R. 6201). (WHG client summary).

- **March 14:** The House passed the Families First Coronavirus Response Act (H.R. 6201) by a vote of 363-40 (details). Relating to health care, the approved version contained several changes – most notably, the House approved a Medicaid Federal medical assistant percentage (FMAP) of 6.2 percent instead of the initially proposed 8 percent.

- **March 12:** Sen. Tina Smith (D-MN) led a group of Democratic Senate colleagues in introducing the Free COVID-19 Testing Act (Details).

- **March 11:** House Democrats introduced the Families First Coronavirus Response Act (H.R. 6201) – a package of bills intended to bolster the federal government's response to the coronavirus outbreak and address the safety and financial impacts in communities (WHG client summary).

- **March 10:** House Education and Labor Committee Chairman Bobby Scott (D-VA), Rep. Donna Shalala (D-FL), and Committee Democrats introduced the COVID-19 Worker Protection Act of 2020 (H.R. 6139). The bill was incorporated into introduced version of H.R. 6201, but was not included in the final version approved by the House. (WHG client summary).

- **March 6:** The President signed the $8.3 billion emergency supplemental appropriation bill to address the COVID-19 outbreak into law. (WHG client summary).

- **March 5:** The Senate voted 91-1 to pass H.R. 6074, the House-passed $8.3 billion emergency supplemental appropriation to address the coronavirus (COVID-19) outbreak. The sole "no" vote was from Senator Rand Paul (R-KY). (WHG client summary).

Oversight and Other

- **April 2:** House Oversight and Reform (O&R) Committee Chairwoman Carolyn Maloney (D-NY) sent a letter to Pharmaceutical Research and Manufacturers of America (PhRMA) requesting its member drug companies to commit to setting affordable list prices for medications, including vaccines, that may be used to prevent or treat COVID-19.

- **April 2:** House Oversight and Reform Committee Chairwoman Carolyn Maloney (D-NY) released a series of documents obtained from the Federal Emergency management Agency (FEMA) showing critical shortages of medical supplies in Delaware, the District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia.

- **April 2:** House Speaker Nancy Pelosi (D-CA) announced the formation of the House Select Committee on the Coronavirus Crisis – a select bipartisan oversight panel that will be chaired by Majority Whip Jim Clyburn (D-SC). The Select Committee will be charged with overseeing the implementation of appropriated funds made available through COVID-19 response legislation.

- **April 1**: Fourteen House Committee Chairs sent a letter to Office of Management and Budget (OMB) Acting Director Russell Vought requesting an immediate extension of public comment periods, hearings and meetings due to the ongoing COVID-19 pandemic.

- **March 30:** Sens. Michael Bennet (D-CO) and John Barrasso (R-WY) led a bipartisan, bicameral letter urging HHS Secretary Alex Azar to provided financial resources and flexibilities, authorized by the CARES Act, immediately available to rural hospitals.

- **March 30:** The Congressional Research Service (CRS) released a Legal Sidebar that discusses how certain congressional or executive actions intended to increase access to medical countermeasures might be viewed under the rules of the international trade regime, including: (1)

exclusion from patent protection; (2) compulsory licensing of patented products; and (3) increasing domestic capacity.

- **March 27:** In a joint statement, Senate Finance Ranking Member Ron Wyden (D-OR), Senate HELP Ranking Member Patty Murray (D-WA), House Ways and Means Chairman Richard E. Neal (D-MA), House Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ), and House Education and Labor Chairman Bobby Scott (D-VA) called for measures to: (1) eliminate out-of-pocket costs for all medical care associated with COVID-19, including treatment; (2) increase health care tax credits and expand eligibility for such premium assistance; (3) open a special enrollment period for the Affordable Care Act's exchanges; and (4) increase the Federal medical assistance percentage (FMAP) (i.e., the federal share of costs) to incentivize non-expansion states to expand Medicaid.

- **March 27:** Sens. Tammy Baldwin (D-WI), Elizabeth Warren (D-MA), and Cory Booker (D-NJ) led a group of their Democratic colleagues in a letter urging the FDA to end its men who have sex with men (MSM) deferral policy due to its discriminatory nature as well as to help address the nationwide shortage of donate blood spurred by the COVID-19 pandemic. The deferral policy prohibits MSM from donating blood during the one-year period after last sexual contact.

- **March 26:** The Congressional Research Service released a summary about the resources and assistances available through the National Consortium of Telehealth Resource Centers in helping stakeholders respond to COVID-19 through the use of telehealth.

- **March 25:** The Congressional Research Service released a summary of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074), which was signed into law on March 6, 2020.

- **March 25:** House Oversight Subcommittee on Economic and Consumer Policy Chairman Raja Krishnamoorthi (D-IL) and Rep. Katie Porter (D-CA) sent letters to the Carbon Health Medical Group, Everlywell, Inc., and Nurx, Inc., seeking information about each company's at home coronavirus test kits. The letters follow a warning issued by the Food and Drug Administration (FDA) against using "unauthorized fraudulent" at-home test kits.

- **March 21:** House Oversight Committee Democratic leaders sent a letter to the Department of Health and Human Services, requesting a briefing on the Trump administration's plans to acquire and distribute personal protective equipment and ventilators; to increase hospital bed capacity; to use the Defense Production Act; and to work with FEMA in the acquisition and distribution of personal protective equipment and medical supplies.

- **March 19:** House Oversight Committee Democratic leaders sent a letter to the Trump Administration, seeking a copy of its plans to produce, distribute, and conduct coronavirus testing across the country.

- **March 19:** Sen. Chris Murphy (D-CT) led 16 Senate Democrats in a letter urging seven private health insurers to fully cover testing and treatment for COVID-19 and associated health complications with no cost-sharing. (WHG client summary).

- **March 17:** House E&C Committee Chairman Frank Pallone, Jr. (D-NJ) and other Democratic committee leaders sent a letter, urging the Federal Trade Commission (FTC) to take immediate action to protect consumers from price gouging during the COVID-19 public health emergency.

- **March 16:** Senate Democrats released their "Economic and Community Services Proposal," which includes proposals to address lost wages, paid sick days and loan payment relief; small business and local economic relief; and housing, food security, and education.

- **March 13:** More than 100 House Democrats sent a letter, urging HHS Secretary Alex Azar to establish a Special Enrollment Period (SEP) for qualified individuals to obtain coverage through the federal exchange or state-based exchanges during the COVID-19 pandemic. Of note, Washington and Massachusetts have announced that they will offer a SEP due to the pandemic through April 8 and 25, respectively.

- **March 13:** The Congressional Research Service (CRS) released a brief report discussing the potential challenges of COVID-19 to the United States' blood supply. (WHG client summary).

- **March 9:** The Congressional Research Service (CRS) released a summary of FAQs regarding the development and regulation of domestic diagnostic testing for COVID-19.

- **March 6:** Senate Special Committee on Aging Chairwoman Susan Collins (R-ME) and Ranking Member Bob Casey (D-PA) led a bipartisan letter to HHS Secretary Alex Azar, urging the Department to "consider the unique health needs of older Americans in all aspects of the domestic response." (WHG client summary).

- **March 4:** House Ways and Means Committee Chairman Richard Neal (D-MA) and Rep. Suzan DelBene (D-WA) sent a letter to the CMS Administrator Seema Verma, requesting information on how the agency is assisting skilled nursing facilities (SNFs) and nursing facilities (NFs) to prevent the spread of coronavirus (COVID-19). The information is due by March 6, 2020. (WHG client summary).