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

Updated May 22, 2020

In response to the novel coronavirus (COVID-19) pandemic, U.S. government agencies have continued the rapid release of fact sheets and guidance documents on a daily 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.

We have also incorporated actionable funding information for stakeholders responding to the COVID-19 pandemic. To view this information, follow the Funding hyperlink below.

ACL; ASPR; CDC; CMS; DOJ; FCC; FDA; FEMA; HHS; HRSA; HUD; LABOR; NIH; OCR; OIG; SAMHSA; SBA; TREASURY; USDA; CONGRESS; WHITE HOUSE; FUNDING OPPORTUNITIES

CENTERS FOR MEDICARE & MEDICAID SERVICES

Waivers and other Emergency Flexibilities

- May 11: CMS announced additional <u>blanket waiver authorities</u> for long-term care service providers, sole community hospitals, Medicare-dependent, small rural hospitals, and hospitals, hospice, and long-term care facilities.
- **April 30:** In follow-up to its March 31st interim final rule with comment period, CMS <u>announced</u> a second set of wide-reaching changes in response to the COVID-19 pandemic (WHG client <u>summary</u>).
- April 23: CMS <u>announced</u> new <u>guidance</u> that will allow independent freestanding emergency departments (IFEDs) to provide care to Medicare and Medicaid beneficiaries during the COVID-19 public health emergency. This is in effect for Colorado, Delaware, Rhode Island, and Texas. (WHG client <u>summary</u>).
- **April 22:** CMS <u>released</u> a virtual <u>toolkit</u> to help states respond to health care workforce shortages by leveraging new emergency flexibilities offered during the public health emergency. The toolkits also contain best practices for states and localities to reference as they implement changes in their respective areas.

- **April 22:** CMS announced additional <u>blanket waivers</u> for Medicare providers, including RHCs, FQHCs, LTCHs, and Intermediate Care Facilities. The changes also include flexibilities around current substitute billing (locum tenens) rules. (WHG client <u>summary</u>).
- April 17: CMS released a Medicare Learning Network (MLN) <u>article</u> outlining additional guidance on new and expanded flexibilities for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), including information on new payment for telehealth services, expansion of virtual communication services, and accelerated/advance payments, among others.
- April 15: CMS released <u>guidance</u> on new waivers for inpatient prospective payment system (IPPS) hospitals, long-term care hospitals (LTCHs), and inpatient rehabilitation facilities (IRFs) stemming from CARES Act changes, with specific guidance on how to code claims for receiving higher payment. CMS also included guidance on waiving the Medicare Part A requirement that patients treated in IRFs receive at least 15 hours of therapy per week.
- **April 9:** CMS <u>announced</u> a new set of waivers for CAHs, SNFs, HHAs, and Hospices. (WHG client <u>summary</u>).
- March 30: CMS <u>announced</u> a landmark array of new waivers and flexibilities for Medicare providers to address the surge in COVID-19 cases. (WHG client summary <u>here</u>).
- 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 13: CMS released a <u>fact sheet</u> (<u>press release</u>) 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
 <u>summary</u>). The transcript and audio recording from a National Stakeholder Call on these
 flexibilities is available <u>here</u>.

State-Specific Disaster Waiver Approvals

- *New* May 22: CMS approved a second round of requested 1135 waiver flexibilities for the state of North Dakota, and a second and third round of requested 1135 flexibilities for the state of Texas.
- *New* May 19: CMS approved an 1135 waiver for the state of Virginia.
- *New* May 18: CMS approved a second, third, and fourth round of requested 1135 waiver flexibilities for the state of Rhode Island.
- *New* May 15: CMS approved an 1135 waiver for the state of Alaska.
- *New* May 14: CMS approved an 1135 waiver for the state of Missouri.
- *New* May 14: CMS approved a second round of requested 1135 waiver flexibilities for the state of Georgia.

- *New* May 13: CMS approved an 1135 waiver for the state of Indiana.
- May 12: CMS approved a second round of requested 1135 waiver flexibilities for the state of Connecticut.
- May 11: CMS approved a second round of requested 1135 waiver flexibilities for the state of Louisiana.
- May 8: CMS approved a second round of requested 1135 waiver flexibilities from each of the states of <u>California</u>, <u>Oregon</u>, <u>Alabama</u>, <u>Massachusetts</u>, <u>Nebraska</u>, <u>Minnesota</u>, and the <u>District of</u> <u>Columbia</u>.
- **May 6:** CMS approved a second round of requested 1135 waiver flexibilities from each of the states of <u>Arizona</u>, <u>Washington</u>, <u>Maryland</u> and <u>New York</u>.
- May 5: CMS approved a second round of requested 1135 waiver flexibilities from each of the states of <u>Arkansas</u> and <u>Iowa</u>.
- April 22: CMS approved an 1135 waiver for the state of Ohio.
- April 20: CMS approved an 1135 waiver for the state of <u>Wisconsin</u>.
- April 21: CMS <u>approved</u> the state of Washington's COVID-19 Public Health Emergency (PHE) section 1115(a) demonstration, "COVID-19 PHE." This approval is the first section 1115(a) demonstration specifically intended to combat the effects of COVID-19 in a state since the President Trump declared the COVID-19 outbreak a national emergency on March 13th.
- **April 14**: CMS <u>announced</u> it has approved 50 emergency waivers (50th waiver was for <u>Utah</u>), 28 state amendments, 9 COVID-related Medicaid Disaster Amendments, and one CHIP COVID-related Disaster Amendment.
- **April 7:** CMS approved Section 1135 waiver requests for <u>Maine</u>, the <u>U.S. Virgin Islands</u>, <u>Nevada</u>, <u>Michigan</u>, and the <u>District of Columbia</u>, bringing the total number to 49.
- **April 2**: CMS approved Section 1135 waiver requests for <u>Georgia</u>, <u>Alaska</u>, <u>Arkansas</u>, and <u>Nebraska</u>, 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 approved 1135 waivers for <u>Montana</u>, <u>Texas</u>, <u>Vermont</u>, and <u>West Virginia</u>, bringing the total number approved to 38. All waivers are available <u>here</u>.
- March 27: CMS <u>announced</u> it approved a total of 34 state applications for 1135 waiver authority to respond to the COVID-19 outbreak. (WHG client <u>summary</u>).

- 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: <u>Kentucky</u>; <u>Rhode Island</u>; <u>Iowa</u>; <u>Indiana</u>; <u>Kansas</u>; <u>Missouri</u>; and <u>Oregon</u>.
- March 23: CMS <u>announced</u> the approval of 1135 waiver requests from 11 states, including:
 <u>Alabama</u>, <u>Arizona</u>, <u>California</u>, <u>Illinois</u>, <u>Louisiana</u>, <u>Mississippi</u>, <u>New Hampshire</u>, <u>New Jersey</u>, <u>New Mexico</u>, <u>North Carolina</u>, and <u>Virginia</u>. Additional Section 1135 approval letters will be posted <u>here</u> as they are issued. (WHG client <u>summary</u>).
- 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.

Infection Control and Prevention

- *New* May 18: CMS <u>issued</u> guidance to assist State and local officials in reopening nursing homes safely (<u>press release</u>, <u>FAQs</u>) (WHG client <u>summary</u>).
- *New* May 13: CMS released a new infection control <u>toolkit</u> for states to guide them in mitigating COVID-19 outbreaks in nursing home facilities, covering key topics such as testing, cohorting, "strike teams", PPE, and transportation, among others. (WHG client summary).
- May 11: CMS Administrator Seema Verma sent a <u>letter</u> to nursing home facilities thanking them for their work and reminding them of key infection control resources.
- May 1: CMS announced a second set of <u>frequently asked questions</u> (FAQs) clarifying requirements and considerations for hospitals and other providers related to the Emergency Medical Treatment and Labor Act (EMTALA).
- **April 30:** CMS <u>announced</u> it is establishing an independent commission (<u>details</u>) to assess how nursing homes are responding to the COVID-19 pandemic.
- April 23: CMS released <u>updated guidance</u> on infection control and prevention protocols for Home Health Agencies to now also include guidance for Religious Nonmedical Healthcare Institutions.
- April 20: CMS released a <u>memorandum</u> that outlines upcoming notification requirements of
 confirmed or suspected COVID-19 cases for nursing homes. While the memorandum previews
 these requirements, CMS states it will codify them formally in forthcoming rulemaking "very
 soon." (WHG client <u>summary</u>).
- **April 19:** CMS issued <u>recommendations</u> to re-open health care systems in communities that have low incidence of COVID-19 and are in Phase 1 of the Guidelines for Opening Up American

Again (<u>press release</u>). This guidance updates <u>previous recommendations</u> on limiting non-essential surgeries and medical procedures during the COVID-19 pandemic (WHG client <u>summary</u>).

- **April 13:** CMS released <u>supplemental information</u> to long-term care facilities on transferring or discharging residents between facilities for COVID-19 cohorting.
- April 7: CMS issued <u>recommendations</u> 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 <u>guidance</u> 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 <u>summary</u>).
- March 17: CMS issued COVID-19 <u>guidance</u> 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 <u>memorandum</u> based on recommendations from the CDC directing <u>nursing homes</u> 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 <u>guidance</u> 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 <u>guidance</u> 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 <u>guidance</u> specific to nursing homes to help control and prevent the spread of the virus (WHG client <u>summary</u>).
- March 4: CMS <u>announced</u> 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 <u>summary</u>).

Personal Protective Equipment (PPE)

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

- May 8: CMS released a Medicare Learning Network (MLN) <u>video</u> explaining recent changes to Medicare coverage and payment for telehealth services.
- May 8: CMS released a Medicare Learning Network (MLN) <u>article</u> describing how Medicare pharmacies and other suppliers may temporarily enroll as independent clinical diagnostic laboratories.
- **April 23:** CMS released a new <u>toolkit</u> for states to help accelerate adoption of broader telehealth coverage policies in the Medicaid and Children's Health Insurance Programs (CHIP) during the COVID-19 pandemic.
- **April 6:** CMS released a <u>video</u> answering common questions about the recent Medicare telehealth expansions.
- **April 3:** CMS released a <u>memo</u> 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 <u>toolkit</u>, this time for long-term care nursing homes. (WHG client <u>summary</u>).
- March 22: CMS released <u>FAQs</u> 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 (<u>here</u>) and one for providers treating end-stage renal disease (<u>here</u>) 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 <u>press release</u> highlighting the telehealth benefits in the agency's Medicare program for use by patients and providers.

Quality Reporting

- **April 28:** CMS issued a Dear Clinician <u>Letter</u> sharing additional details on the MIPS improvement activity related to providers participating in COVID-19 trials.
- **April 27:** CMS <u>clarified</u> for health plan issuers in the individual and small group markets which telehealth services are valid for data submissions to the HHS-operated risk adjustment program.
- **April 20:** CMS <u>announced</u> that clinicians participating in the Merit-based Inceptive Payment System (MIPS) can now earn credit for participating in clinical trials and reporting clinical

information by using the new COVID-19 Clinical Trials improvement activity. (WHG client summary).

- **April 18:** CMS issued a <u>memorandum</u> to all eligible qualified health plan (QHP) issuers announcing reporting flexibilities for the Quality Rating System (QRS), the QHP Enrollee Experience Survey, and Quality Improvement Strategy Programs (QIS). (WHG client summary).
- **April 13:** CMS <u>announced</u> it is postponing the 2019 Benefit year Risk Adjustment Data Validation (RADV) process.
- April 13: CMS recently announced two additional measures in response to the COVID-19 pandemic: one pertaining to Medicare Advantage (MA) risk adjustment, and the other to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. (WHG client summary).

Coding and Reimbursement

- *NEW* May 19: CMS <u>updated</u> its Medicare payment factsheet for COVID-19 diagnostic tests to add additional codes that laboratories may bill Medicare for, including serology tests (WHG client summary).
- April 26: CMS <u>announced</u> (<u>fact sheet</u>) it is suspending its Advance Payment Program to Medicare Part B suppliers effective immediately. It is furthermore "reevaluating" the payment amounts to be paid through its Part A provider-focused Accelerated Payment Program
- **April 15:** CMS <u>announced</u> it is nearly doubling Medicare payment for lab tests that use high-throughput technologies for rapidly detecting COVID-19 cases. (WHG client <u>summary</u>).
- April 7: CMS released a <u>Dear Clinician Letter</u> 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 <u>announced</u> it is expanding advanced and accelerated payments for providers and suppliers to support response efforts to the COVID-19 outbreak (<u>fact sheet</u>). (WHG client <u>summary</u>).
- 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

• **April 23:** CMS released two sets of guidance documents (here and here) affecting individual and group market health plan issuers, Medicare Advantage (MA) sponsors, and Medicare Part D sponsors. (WHG client summary).

- March 24: CMS <u>announced</u> qualified health plans (QHPs) would be permitted to extend payment deadlines and delay the beginning of applicable grace periods for enrollees. (WHG client <u>summary</u>).
- **March 18:** CMS issued <u>FAQs</u> to clarify coverage for the diagnosis and treatment of COVID-19 by catastrophic health plans.
- March 13: CMS released a <u>fact sheet</u> to assist Medicare providers with information related to the price of CDC tests and non-CDC tests for COVID-19. (WHG client <u>summary</u>).
- March 12: CMS issued Frequently Asked Questions (<u>FAQs</u>) 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 <u>guidance</u> to help Medicare Advantage and Part D plans respond to the coronavirus (WHG client <u>summary</u>).

Medicaid & CHIP

- *New* May 14: CMS issued an <u>informational bulletin</u> outlining options for responding to COVID-19 for Medicaid Managed Care Organizations. (WHG client <u>summary</u>).
- May 5: CMS posted a <u>new set</u> of COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and CHIP Agencies addressing new questions on: Emergency Preparedness and Response; Eligibility and Enrollment Flexibilities; Benefit Flexibilities; Cost-Sharing Flexibilities; Financing Flexibilities; Managed Care Flexibilities; Information Technology; and Data Reporting. (WHG client <u>summary</u>).
- **April 30:** Along with the rollout of its second set of wide-reaching regulatory changes in response to the COVID-19 pandemic (WHG client <u>summary</u>), CMS released a Medicaid and Basic Health Program-specific fact sheet.
- April 13: CMS <u>released</u> additional FAQs on enhanced federal funding for Medicaid and CHIP agencies, along with additional relevant information on recent COVID-19-related congressional action.
- **April 2:** CMS updated its set of FAQs providing additional information on coronavirus response strategies for Medicaid and CHIP agencies (WHG client <u>summary</u>). The most recently updated version of this document is available <u>here</u>.
- March 24: CMS released set of <u>FAQs</u> 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 <u>summary</u>).
- March 17: CMS released sample state plan language in a <u>document</u> 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 <u>fact sheet</u> outlining coverage and benefits related to COVID-19 in Medicaid CHIP.

For State Survey Agencies, Accrediting Organizations

- March 23: CMS <u>released</u> a <u>fact sheet</u> 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 <u>summary</u>).
- 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 13:** The FCC formally <u>opened</u> the application period for its COVID-19 telehealth program at noon ET on April 13, 2020. (WHG client <u>summary</u>).
- **April 2:** The FCC <u>announced</u> it voted to adopt the \$200 million COVID-19 Telehealth Program (<u>details</u>).
- March 30: The Chairman of the Federal Communications Commission (FCC) <u>announced</u> a new plan dedicating \$200 million to support health care facilities standing up telehealth programs in response to the COVID-19 pandemic. (WHG client <u>summary</u>).

FOOD & DRUG ADMINISTRATION

Treatments and Vaccines

- **May 11:** The FDA <u>issued</u> two guidance documents to accelerate the development of novel prevention and treatment options for COVID-19 (WHG client <u>summary</u>).
- May 1: The FDA <u>issued</u> an <u>Emergency Use Authorization (EUA)</u> for the investigational antiviral
 drug remdesivir for the treatment of hospitalized adults and children with COVID-19 (WHG
 client <u>summary</u>).
- April 24: The FDA <u>issued</u> a <u>Drug Safety Communication</u> regarding the known side effects of hydroxychloroquine and chloroquine as treatment for COVID-19. The communication urges that these products only be used in a hospital setting or a clinical trial.
- **April 16**: The FDA is <u>encouraging</u> individuals who have recovered from COVID-19 to donate their plasma through a newly launched <u>website</u> intended to guide recovered patients to local blood or plasma collection centers.

- April 13: FDA <u>issued</u> product specific guidance for <u>chloroquine phosphate</u> and <u>hydroxychloroquine phosphate</u> that provide recommendations on design of bioequivalence studies to support abbreviated new drug applications (ANDAs), among other things (WHG client <u>summary</u>)
- **April 10:** FDA <u>issued</u> an Emergency Use Authorization (EUA) for a blood purification system to treat adults with confirmed COVID-19 infection.
- April 8: FDA <u>issued</u> guidance to provide recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID-19 (WHG client <u>summary</u>).
- **April 1:** FDA <u>announced</u> 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 <u>announced</u> the Coronavirus Treatment Acceleration Program (CTAP), a new program intended to expedite the development of safe and effective life-saving treatments (WHG client <u>summary</u>)
- March 28: FDA <u>issued</u> Emergency Use Authorization (EUA) to allow chloroquine phosphate
 and hydroxychloroquine phosphate products to be distributed and used for patients with COVID19 (WHG client <u>summary</u>).
- March 24: FDA is <u>facilitating</u> 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 <u>issued</u> guidance on conducting clinical trials during the COVID-19 outbreak, including considerations for protocol modifications (WHG client <u>summary</u>).
- March 9: FDA and FTC <u>warned</u> 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)

- **April 28:** The FDA <u>released</u> a FAQ on the Emergency Use Authorization (EUA) for non-surgical face masks and clarifies that these face masks are not authorized to be personal protective equipment, but rather for use by the general public.
- **April 27:** The FDA provided an <u>update</u> on the availability of hand sanitizer and efforts to address safety concerns. The FDA notes that more than 1,500 additional manufacturers have registered with the agency to produce hand sanitizer in line with the FDA's policy.

- **April 10:** FDA <u>issued</u> an EUA to decontaminate N95 or N95-equivalent respirators for reuse by health care workers in the hospital setting. The FDA estimates that this EUA has the potential to decontaminate approximately 4 million respirators per day.
- March 27: FDA <u>issued</u> two Emergency Use Authorizations (EUAs) to increase the supply of ventilators and respirators. The first <u>EUA</u> allows for the emergency use in health care settings of certain ventilators, ventilator tubing connectors, and ventilator accessories, while the second <u>EUA</u> was issued for certain imported non-National Institute for Occupational Safety and Health (NIOSH) approved respirators (WHG client <u>summary</u>)
- March 26: FDA <u>issued</u> 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 <u>provided</u> instructions to manufacturers to import personal protective equipment (PPE) and other devices (WHG client summary)
- **March 22:** FDA <u>issued</u> guidance to expand the manufacturing and availability of ventilators and other respiratory devices, such as CPAP machines (WHG client <u>summary</u>).
- March 20: FDA <u>issued</u> 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 <u>summary</u>).
- March 11: FDA <u>issued</u> a letter to health care providers on recommendations for mask and gown conservation (WHG client <u>summary</u>).
- March 2: FDA and CDC <u>took action</u> 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

- *NEW* May 21: The FDA <u>announced</u> the removal of 27 antibody tests from the "notification list" of tests being offered under the agency's policy for COVID-19 (WHG client <u>summary</u>).
- *NEW* May 16: The FDA <u>issued</u> the first Emergency Use Authorization (EUA) for a standalone at-home sample collection kit that can then be sent to specified laboratories for COVID-19 diagnostic testing.
- *NEW* May 14: The FDA <u>issued</u> revised guidance regarding the policies for COVID-19 testing during the public health emergency (PHE) (WHG client <u>summary</u>)
- May 8: The FDA <u>issued</u> the first Emergency Use Authorization (EUA) for a COVID-19 antigen test, a new category of diagnostic tests during the COVID-19 pandemic. The antigen test detects fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. Results can be provided within minutes.

- May 8: The FDA <u>issued</u> the first EUA for a diagnostic test with the option of using home-collected saliva samples.
- May 7: The FDA <u>issued</u> an Emergency Use Authorization (EUA) to Sherlock BioSciences for the Sherlock CRISPR SARS-CoV-2 Kit. This is the first EUA issued for CRISPR technology, which looks for the specific RNA or DNA sequence of COVID-19 in upper respiratory systems. The use of this test is limited to clinical laboratories.
- May 4: The FDA <u>revised</u> its <u>March 16 policy</u> on antibody tests by requiring manufacturers to apply for Emergency Use Authorization (EUA) within 10 days of the test being on the market.
- **April 29:** The FDA <u>established</u> an Emergency Use Authorization (EUA) pathway for COVID-19 antibody tests that have been evaluated in an independent validation study performance at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by a designated government agency (WHG client summary).
- April 21: The FDA <u>issued</u> an EUA for the first test for patient at-home sample collection. Under this EUA, LabCorp may test self-collected samples by patients using the LabCorp COVID-19 home collection kit.
- **April 18**: The FDA provided an <u>update</u> on serological tests intended to detect antibodies to COVID-19, which includes the agency's approach to expand access, how the tests work, data validation, and education for frontline workers and states.
- **April 16:** The FDA <u>announced</u> a new partnership between the Gates Foundations, UnitedHealth Group, Quantigen, and U.S. Cotton to manufacture a new type of swab for COVID-19 testing that can be produced at scale.
- **April 7:** FDA announced an <u>update</u> on serological tests designed to detect antibodies and determine immunity to COVID-19. It is the hope of the agency that these tests will be used to determine when patients have recovered from COVID-19 and can return to work. To date, the FDA has issued one Emergency Use Authorization for a serological test.
- **April 6:** To date, the FDA has <u>issued</u> 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 <u>issued</u> 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 <u>issued</u> 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 <u>issued</u> 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 <u>issued</u> 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 <u>announced</u> new state flexibility to authorize diagnostic test and updated existing policy to include commercial manufacturers (WHG client <u>summary</u>).
- March 16: FDA <u>issued</u> 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 <u>issued</u> the fourth COVID-19 Emergency Use Authorization (EUA) diagnostic to Thermo Fisher for its TaqPath COVID-19 Combo kit.
- March 12: FDA <u>issued</u> 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 <u>issued</u> Emergency Use Authorizations (EUAs) to two public health labs in New York for diagnostics to test COVID-19.
- **February 29:** FDA <u>issued</u> 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 <u>summary</u>).

Medical Devices

- May 6: The FDA <u>issued</u> final guidance on notifying the Center for Devices and Radiological Health (CDRH) of a permanent discontinuance or interruption in manufacturing a device during the COVID-19 <u>public health</u> emergency (PHE) (WHG client <u>summary</u>).
- **April 30:** The FDA <u>issued</u> an Emergency Use Authorization (EUA) for a ventilator developed by the National Aeronautics and Space Administration (NASA), specifically designed to treat patients with COVID-19.
- **April 23:** The FDA issued <u>guidance</u> on non-invasive fetal and maternal monitoring devices to increase the availability and capability of these devices used to monitor patients during the pandemic.
- **April 23:** The FDA issued <u>guidance</u> to expand the availability and capability of imaging devices used to diagnose and monitor lung disease in patients during the pandemic.
- March 24: FDA <u>issued</u> 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 <u>summary</u>).
- March 20: FDA <u>issued</u> guidance to expand the use of devices to remotely monitor patient's vital signs (WHG client <u>summary</u>).

Food and Drug Safety and Supply Chain

- **April 28:** The FDA posted <u>information and resources</u> to assist manufacturers submitted generic drug applications with bioequivalence studies that may be impacted by COVID-19.
- April 20: The FDA has <u>expanded</u> a temporary policy to allow state-licensed pharmacies and federal facilities to compound certain human drugs for hospitalized patients during the COVID-19 pandemic.
- **April 16:** The FDA <u>issued</u> a temporary policy to allow outsourcing facilities to compound certain human drugs for hospitalized individuals during the COVID-19 pandemic.
- **March 27:** FDA <u>issued</u> guidance on the importance of notifying the agency of any discontinuance or interruption of drug and biological product manufacturing.
- March 27: FDA <u>issued</u> a letter to stakeholders detailing the danger of taking chloroquine phosphate products intended to treat disease in aquarium fish.
- **March 26:** FDA <u>issued</u> guidance on a temporary policy regarding nutrition labeling of certain packaged food during COVID-19 public health emergency.
- March 17: FDA <u>issued</u> a temporary policy for FDA Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements during the COVID-19 emergency.

Blood Supply

• **April 2:** FDA <u>issued</u> 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 <u>summary</u>).

CENTERS FOR DISEASE CONTROL & PREVENTION

Note: A complete list of CDC guidance documents is available <u>here</u>.

Funding Opportunities and Awards

- April 23: CDC will <u>award</u> \$631 million in supplemental funding to 64 jurisdictions to support the COVID-19 response through the existing Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) cooperative agreement.
- April 21: CDC forecasted a funding opportunity titled, "ATSDR's Partnership to Promote Local Efforts To Reduce Environmental Exposure COVID-19 Supplement" (CDC-RFA-TS20-20010101SUPP20). This funding opportunity is only available to organizations that received funding under Component 1 of CDC-RFA-TS20-2001 "ATSDR's Partnership to Promote Local Efforts to Reduce Environmental Exposures (APPLETREE)". The estimated post date is May 1, 2020 and the estimated application due date is May 8, 2020.
- April 14: CDC issued a funding opportunity titled, "Strengthening Public Health Systems and Services through National Partnerships to Improve and Protect the Nation's Health" (CDC-RFA-

OT18-18020301SUPP20). Approximately \$46.7 million was made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074) (i.e., Phase I COVID-19 bill). The anticipated award date is August 31, 2020. The application deadline is May 14, 2020. (WHG client summary).

- April 6: CDC will <u>award</u> \$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). Approximately \$40 million was made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (H.R. 6074) (i.e., Phase I COVID-19 bill). The application deadline is May 31, 2020.
- March 31: CDC released <u>Frequently Asked Questions</u>: 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 <u>interim guidance</u> regarding Components A and B Supplemental Funding.

Treatment

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

For Providers and Public Health Professionals

- May 1: CDC launched the <u>SARS-CoV-2 Sequencing for Public Health Emergency Response</u>, <u>Epidemiology and Surveillance (SPHERES)</u> consortium a network of laboratories that will conduct real-time sequencing of COVID-19 (WHG client <u>summary</u>).
- **April 30:** CDC released new <u>resources</u> on COVID-19 contact tracing, including <u>training</u> guidance and <u>resources</u>, <u>preliminary criteria for the evaluation of digital contact tracing tools</u>, and <u>principles of contact tracing</u>.

- **April 17:** released guidance on completing the <u>Human Infection with 2019 Novel Coronavirus</u> Person Under Investigation (PUI) and Case Report Form.
- April 3: CDC launched <u>COVIDView</u> 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 <u>contingency and crisis capacity strategies</u> about decontamination and reuse of filtering facepiece respirators (FFRs) (WHG client <u>summary</u>).
- 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 <u>Interim Guidelines</u> for Collecting, Handling, and Testing Clinical Specimens from Persons for COVID-19.
- March 25: CDC released <u>preparedness checklists</u> for hospitals and healthcare professionals preparing for patients with suspected or confirmed COVID-19.
- March 24: CDC issued <u>Interim Additional Guidance</u> for Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed COVID-19 in Outpatient Hemodialysis Facilities.
- March 18: CDC released <u>Prepare to Care for COVID-19</u> 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 <u>FAQs for healthcare professionals</u> 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 <u>announced</u> 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

New May 20: CDC <u>released</u> resources to assist states to reopen, which includes <u>CDC</u>
 <u>Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again.</u>

- *New* May 14: CDC released reopening guidance for workplaces, mass transit, schools, child care programs, restaurants and bars, and youth programs and camps.
- **April 3:** CDC released new <u>recommendations</u> for individuals to wear cloth face coverings in public settings where other <u>social distancing measures</u> 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 <u>Released</u> mitigation strategies to help stop the spread of the coronavirus (WHG client <u>summary</u>).
- **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

- *New* May 22: HHS <u>announced</u> \$500 million in payments from the Provider Relief Fund to the Indian Health Service (IHS) and tribal hospitals, clinics, and urban health centers to support the tribal response to COVID-19.
- *New* May 22: HHS <u>announced</u> the distribution of \$4.9 billion to skilled nursing facilities (SNFs) impacted by COVID-19. The agency details that each certified SNF with 6 or more beds will receive \$50,000, plus \$2,500 per bed (WHG client <u>summary</u>)
- *New* May 21: HHS announced that under Operation Warp Speed, and through a \$1.2 billion agreement with BARDA, HHS and AstraZeneca are collaborating to make available at least 300 million doses of a coronavirus vaccine called AZD1222. The first doses could be delivered as early as October 2020.
- *New* May 20: HHS released a <u>statement</u> explaining that providers have until June 3, 2020, to accept the Terms and Conditions and submit their revenue information to keep or apply for an additional payment from the Provider Relief Fund \$50 billion General Distribution.
- *New* May 20: HHS <u>awarded</u> \$225 million appropriated by the Paycheck Protection Program and Health Care Enhancement Act to Rural Health Clinics (RHCs) for COVID-19 testing. A state-by-state breakdown of the funding is available <u>here</u>.
- *New* May 19: HHS <u>announced</u> a partnership with a team of private industry partners led by Phlow Co., to expand pharmaceutical manufacturing in the U.S. for production of medicines needed during the COVID-19 response and future public health emergencies.
- *New* May 18: HHS <u>announced</u> the CDC will provide \$10.25 billion to states, territories, and local jurisdictions through CDC's existing Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases cooperative agreement, while the IHS will provide

- \$750 million to IHS, tribal, and urban Indian Health programs to expand testing capacity and testing-related activities. The list of funding recipients is available <u>here</u>.
- *New* May 15: The Trump Administration announced the framework and leadership for
 Operation Warp Speed, the administration's national public-private partnership to accelerate the
 development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and
 diagnostics.
- *New* May 14: Through AHRQ, HHS <u>issued</u> a new funding opportunity announcement (FOA) that will award \$5 million to support novel, high-impact studies that evaluate the responsiveness of health care delivery systems, health care professionals, and the overall U.S. health care system to the COVID-19 pandemic. Applications are due June 15; the FOA is available <u>here</u>. (WHG client summary)
- *New* May 13: Through HRSA, HHS has <u>awarded</u> \$15 million to 159 organizations across five health workforce programs to increase telehealth capabilities in response to the COVID-19 pandemic. The awards are funded by the CARES Act. More information about the recipients is available here.
- May 12: HHS <u>updated</u> the Provider Relief Fund data to include the list of providers that received a payment from the \$50 billion General Distribution and/or the \$10 billion Rural Targeted Allocation and who have attested to payments and agreed to the Terms and Conditions as of May 6, 2020.
- May 9: HHS <u>announced</u> that ASPR has released an allocation plan for distributing donated remdesivir to hospitalized COVID-19 patients. The process was initiated May 7 to deliver cases of the drug to select states.
- May 8: HHS <u>released</u> data detailing the \$12 billion COVID-19 High-Impact Allocation from the Provider Relief Fund.
- May 7: The Strategic National Stockpile, managed by HHS's ASPR, has <u>deployed</u> 50 portable dialysis machines and supplies to New York City and Long Island intensive care units to provide surge capacity for facilities treating patients with COVID-19.
- May 7: HHS awarded nearly \$583 million to 1,385 HRSA-funded health centers to expand COVID-19 testing. The funds were appropriated through the Phase 3.5 relief bill. A list of award recipients is available here.
- May 7: HHS <u>extended</u> the deadline, from 30 days to 45 days, for health care providers to attest to receipt of payments from the Provider Relief Fund and accept the <u>Terms and Conditions</u>.
- May 6: The Trump administration <u>published</u> provider-level data on where HHS has sent Provider Relief Fund dollars. The administration also posted a <u>breakdown</u> detailing how much of the initial \$30 billion in general Provider Relief Fund distributions went to each congressional district (WHG client <u>summary</u>).
- **May 1**: The HHS Office of Minority Health <u>announced</u> a competitive funding opportunity for up to \$40 million. The successful applicant will develop and coordinate a network of national, state,

territorial, tribal, and local organizations to deliver COVID-19-related information to racial and ethnic minorities as well as rural and socially vulnerable communities. <u>Applications</u> are due by May 11, 2020.

- May 1: HHS <u>began distributing</u> targeted payments from the Provider Relief Fund to hospitals in high-impact areas and to rural providers.
- April 30: Through HRSA, HHS <u>awarded</u> \$20 million appropriated under the CARES Act to increase telehealth access and infrastructure for the COVID-19 response. HRSA's Maternal and Child Health Bureau (MCHB) awarded \$15 million and its Federal Office of Rural Health Policy (FORHP) awarded \$5 million.
- **April 28**: HHS <u>announced</u> that it has begun releasing an additional \$20 billion of the \$50 billion general distribution from the Provider Relief Fund to Medicare facilities and providers impacted by COVID-19. \$30 billion was released earlier this month. More information is available <u>here</u>.
- April 27: HHS <u>announced</u> that HRSA has launched a new COVID-19 Uninsured Program <u>Portal</u>, enabling health care providers to submit claims for reimbursement of coronavirus-related treatment provided to uninsured individuals on or after February 4, 2020.
- April 27: HHS <u>announced</u> that SAMHSA has awarded \$250 million in emergency COVID-19 funding to Certified Community Behavioral Health Clinics (CCBHC). The grants are intended to increase access and improve the quality of community mental and substance use disorder (SUD) treatment services during the pandemic. A list of awardees is available here.
- April 24: HHS <u>announced</u> that the Administration for Children and Families (ACF) is releasing \$45 million appropriated by the CARES Act to states, territories, and tribes to support child welfare services during the COVID-19 pandemic.
- **April 23**: Through HRSA, HHS has awarded (<u>press release</u>) nearly \$5 million to Poison Control Centers across the country to improve their capacity to respond to increased calls due to the COVID-19 pandemic. A list of award recipients is available <u>here</u>.
- **April 23**: HHS <u>announced</u> it is extending the deadline for hospitals to submit data that will inform how \$10 billion is distributed to areas highly impacted by COVID-19. The new deadline is Saturday, April 25 by 3PM ET.
- April 23: HHS <u>announced</u> the CDC will award \$631 million in CARES Act funding to state and local jurisdictions through the existing Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases cooperative agreement. More information about the awards is available here.
- **April 22:** HHS <u>announced</u> its plan for allocating and disseminating the remaining \$70B of the \$100B appropriated to the Provider Relief Fund under the CARES Act (WHG client <u>summary</u>).
- April 22: HHS <u>announced</u> that \$165 million was awarded to HRSA to support rural hospitals and HRSA-funded Telehealth Resource Centers (TRCs).

- April 21: The Office of the Secretary sent a letter to administrators requesting that all hospitals report certain data by April 23, 2020. The data will be used to inform forthcoming targeted relief payments from the Provider Relief Fund authorized under the CARES Act (WHG client summary).
- **April 21:** HHS <u>announced</u> that <u>OIG</u>, <u>ONC</u>, and <u>CMS</u> are working together to provide additional flexibility for the implementation and enforcement of the interoperability, information blocking, and certification final rules due to the COVID-19 pandemic.
- **April 21:** HHS <u>announced</u> \$955 million in grants from the ACL to help communities meet the needs of older adults and people with disabilities as they work to minimize the spread of COVID-19 (WHG client <u>summary</u>).
- **April 20:** Through SAMHSA, HHS <u>awarded</u> FY 2020 Emergency COVID-19 grants totaling \$110 million. The grants will provide up to \$2 million for state awardees and up to \$500,000 for territory and tribal awardees for 16 months. More information about the grants is available here.
- **April 20:** HHS <u>announced</u> that Oracle has donated an <u>online platform</u> to collect real-time, crowd-sourced medical data related to COVID-19.
- **April 16:** HHS <u>announced</u> a new contract with General Electric, in partnership with Ford, for ventilator production under the DPA. GE has agreed to produce 50,000 ventilators by July 13. In total, HHS has finalized contracts to produce or acquire over 41,000 ventilators by the end of May, and more than 187,000 ventilators by the end of 2020.
- **April 15:** Through HRSA, HHS <u>awarded</u> \$90 million to Ryan White HIV/AIDS Program recipients for COVID-19 prevention, preparation, and response. The funding was made available via the CARES Act. More information about the award recipients is available <u>here</u>.
- April 14: HHS issued a <u>press release</u> announcing that the Administration for Children and Families (ACF) will be releasing CARES Act funding to support the Child Care and Development Block Grant. More information about the additional \$3.5B available to states is available <u>here</u>.
- April 13: HHS <u>announced</u> five new contracts for ventilator production under the Defense Production Act (DPA), as well as two other contracts for ventilator production. In total, HHS contracts will supply 6,190 ventilators for the Strategic National Stockpile by May 8 and 29,510 by June 1.
- **April 10:** Secretary Azar sent a letter to hospital administrators detailing FAQs about the hospital, hospital laboratory, and acute care facility data reporting requested by Vice President Pence on March 29, 2020 (WHG client summary).
- **April 10:** The HHS Office for Human Research Protections (OHRP) issued (<u>press release</u>) guidance on COVID-19 for investigators, institutional review boards, and institutions conducting human subjects research during the COVID-19 pandemic.
- **April 10:** HHS issued a <u>press release</u> explaining how the first \$30 billion of the \$100 billion Provider Relief Fund created by the Coronavirus Aid, Relief, and Economic Security (CARES)

Act has been allocated and disseminated. The Department also provided insight into how it will distribute the remaining \$70 billion (WHG client <u>summary</u>).

- **April 8:** The HHS Office of the Assistant Secretary for Health <u>issued</u> new <u>guidance</u> under the Public Readiness and Emergency Preparedness Act authorizing licensed pharmacists to order and administer COVID-19 tests that the FDA has authorized.
- **April 8:** HHS <u>announced</u> that Philips has signed a contract under the Defense Production Act (DPA) to make 2,500 ventilators by the end of May, with 43,000 expected by the end of December.
- **April 8:** HHS <u>announced</u> that effective today the Indian Health Service (IHS) is expanding telehealth services in response to the COVID-19 pandemic. Telehealth services can be provided regardless of diagnosis and are not limited to COVID-19 treatment.
- **April 8:** HHS <u>announced</u> HRSA has awarded more than \$1.3 billion to 1,387 health centers. The funding was appropriated through the CARES Act. Information about who received funding and the amount received is available <u>here</u>.
- April 8: HHS <u>announced</u> the federal government has reached a deal with DuPont to deliver 450,000 TYVEK® suits to the U.S. this week. HHS expects to receive another 2.25 million TYVEK® suits over the next five weeks and has the option to continue purchasing up to 4.5 million TYVEK suits.
- **April 8:** HHS <u>announced</u> that General Motors has signed a contract under the Defense Production Act to make 30,000 ventilators by the end of August, with more than 6,000 expected to be available by June 1.
- **April 6:** HHS <u>announced</u> 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 <u>issued</u> an <u>open</u> <u>letter</u> 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 (WHG client <u>summary</u>).

OFFICE FOR CIVIL RIGHTS

- May 5: OCR issued additional <u>guidance</u> reminding covered health care providers that the HIPAA Privacy Rule requires authorization be obtained from patients before media and film crews are granted access to facilities where patients' protected health information (PHI) will be accessible.
- **April 9:** OCR <u>announced</u> it will not impose penalties for HIPAA violations on covered entities or business associates participating in good faith operation of COVID-19 testing sites during the public health emergency. The <u>enforcement discretion</u> is effective immediately and is retroactive to March 13, 2020.

- April 2: OCR <u>announced</u> 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 <u>issued</u> a <u>bulletin</u> 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: <u>enforcement discretion</u> to allow providers to provide telehealth communications remotely; <u>disclosure of protected health information</u> without prior HIPAA authorization; and the <u>ability for providers to share information</u> with the CDC, family members of patients, and others (WHG client <u>summary</u>).
- **March 20:** OCR <u>issued</u> guidance on telehealth remote communications following its <u>Notification</u> <u>of Enforcement Discretion</u> during the COVID-19 nationwide public health emergency.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

- **April 13:** BARDA <u>announced</u> it is providing support to the American Red Cross; Emergent BioSolutions; Grifols USA; and SAb Biotherapeutics, Inc., to facilitate development of convalescent plasma and hyperimmune globulin immunotherapies for COVID-19 patients.
- March 30: BARDA <u>announced</u> 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 <u>announced</u> will provide support for a U.S. <u>Phase 2/3 clinical</u> 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 <u>announced</u> a public-private partnership to create a high-speed, high-volume, emergency drug packaging solution using low-cost prefilled syringes (WHG client <u>summary</u>).
- March 18: BARDA <u>announced</u> 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 <u>provided</u> advanced support to rapidly develop two diagnostic tests for COVID-19, Simplexa COVID-19 Direct Assay and QIAstat-Dx RPS2 test.
- March 9: ASPR <u>announced</u> 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 <u>summary</u>).

- March 4: ASPR <u>announced</u> its intent to purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile.
- **February 18:** ASPR announced collaboration with <u>Janssen</u> and <u>Sanofi</u> for the development of COVID-19 therapeutics and vaccines, respectively.

OFFICE OF THE INSPECTOR GENERAL

- *New* May 14: OIG updated FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- May 8: OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- May 1: OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- **April 24:** OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- **April 6:** OIG <u>released</u> 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 (WHG client summary).
- **April 3:** OIG released a <u>statement</u> explaining that it will not impose administrative sanctions under the Federal anti-kickback statute for actions covered under the blanket waiver <u>issued</u> 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 <u>stated</u> 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 <u>advisory opinions</u> (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 <u>message</u> describing its efforts to minimize the burden on providers while rooting out bad actors during the COVID-19 pandemic.
- March 17: OIG released a <u>statement</u> 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.

DEPARTMENT OF LABOR

• May 6: The Department of Labor <u>awarded</u> a new wave of <u>Dislocated Worker Grants (DWGs)</u> to Missouri, New Mexico, Oklahoma, South Carolina and the Virgin Islands. DWGs may be used to

provide eligible participants with disaster-relief employment, as well as employment and training activities.

- May 5: The Department of Labor <u>announced</u> that <u>Dislocated Worker Grants (DWG)</u> to funding, made available to states under the CARES Act to temporarily hire workers to respond to COVID-19, can be used for contact tracing. Information on approved awards is available here.
- May 1: Employee Benefits Security Administration (EBSA) published <u>updated COBRA model</u> <u>notices</u> (also available in Spanish) regarding the extension of time frames for group health plans, as well as <u>Frequently Asked Questions</u> for beneficiaries (<u>press release</u>).
- **April 11:** The Employee Benefits Security Administration (EBSA) released <u>FAQs</u> regarding implementation of the Families First Coronavirus Response Act, the CARES Act and other health coverage issues related to COVID-19. The FAQs discuss requirements on health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans), including what items and services must be covered, as well as telehealth and other remote care services.
- **April 10:** Employment and Training Administration releases guidance to states on the Pandemic Emergency Unemployment Compensation program (WHG client <u>summary</u>).
- **April 5:** Employment and Training Administration releases guidance to states on the Pandemic Unemployment Assistance program (WHG client summary).
- **April 4:** Employment and Training Administration releases guidance to states on the Federal Pandemic Unemployment Compensation program (WHG client <u>summary</u>).

NATIONAL INSTITUTES OF HEALTH

- *NEW* May 19: The NIH <u>announced</u> the launch of a study to examine the effects of COVID-19 during and after pregnancy. The study will analyze medical records of 21,000 women to determine whether changes to healthcare delivery led to higher rates of pregnancy-related complications and cesarean delivery during the public health emergency.
- *NEW* May 14: The NIH announced the launch of a clinical trial of hydroxychloroquine and azithromycin to treat COVID-19. The trial will enroll 2,000 adults with confirmed cases of COVID-19 across the United States.
- May 4: The NIH <u>announced</u> a new study to help determine the rate of COVID-19 in children and their family members.
- **April 29:** The NIH <u>announced</u> preliminary results from the Remdesivir clinical trial that indicate the treatment accelerates recovery from advanced COVID-19.
- **April 29:** The NIH <u>announced</u> the launch of Rapid Acceleration of Diagnostics (RADx), a national initiative aimed at speeding innovation, development, and commercialization of COVID-19 diagnostic technologies (WHG client <u>summary</u>).

- April 21: The NIH <u>announced</u> the first <u>treatment guidelines for COVID-19 patients</u>, intended for healthcare providers (WHG client <u>summary</u>)
- April 17: The NIH <u>announced</u> a public-private partnership to accelerate the development of COVID-19 vaccine and treatment options. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership aims to develop an international strategy for a coordinated research response to COVID-19 (WHG client summary)
- **April 10:** The NIH <u>announced</u> the launch of study to examine the number of undetected cases of COVID-19. The aims to quantify how many adults in the United States without a confirmed case of COVID-19 have antibodies to the infection.
- **April 9:** NIH <u>announced</u> the launch of a clinical trial for hydroxychloroquine as a potential therapy for COVID-19 (WHG client <u>summary</u>)
- March 23: NIH <u>announced</u> the launch of a <u>website</u> 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 <u>announced</u> 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 <u>announced</u> 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 TREASURY

- May 8: Treasury and the IRS <u>released</u> updated state-by-state figures for Economic Impact Payments. In the first four weeks, approximately 130 million individuals received payments worth more than \$200 billion.
- May 5: Treasury Secretary Steven Mnuchin and Secretary of the Interior David Bernhardt issued a <u>joint statement</u> regarding the distribution of the Coronavirus Relief Fund (\$8 billion made available in the CARES Act) to Native American tribes (WHG client <u>summary</u>).
- **April 29:** Treasury issued an <u>interim final rule</u> authorizing eligible lenders to use alternative criteria to calculate the maximum loan amount for Paycheck Protection Program (PPP) loans provided to seasonal employers (WHG client <u>summary</u>).
- **April 16:** Treasury <u>announced</u> that information about the Coronavirus Relief Fund for states, tribal governments, and eligible local governments is available on its <u>website</u>. This includes information about what local and tribal governments need to do to access funds, as well as how funding amounts will be determined. An electronic <u>form</u> must be submitted by eligible local and tribal governments to provide payment information and supporting documentation by April 17, 2020 (WHG client <u>summary</u>).

- April 9: Treasury Department and Federal Reserve, along with other federal agencies, took several steps to provide economic relief to small and medium-sized businesses, households, and states and local governments affected by the COVID-19 pandemic, including the issuance of interim final rule (WHG client summary).
- March 31: The Treasury Department and the IRS <u>launched</u> 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 <u>announced</u> 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 <u>revealed</u> 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 <u>announced</u> 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 <u>announced</u> 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 <u>announced</u> that high deductible health plans (HDHPs) are able to cover coronavirus costs without cost-sharing.

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

- *New* May 22: USDA announced that Arkansas was approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- *New* May 20: USDA announced that Kentucky, Tennessee, and DC were approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- *New* May 20: USDA announced that it approved 13 additional states Connecticut, Georgia, Illinois, Indiana, Maryland, Massachusetts, Michigan, New Jersey, Ohio, Oklahoma, Pennsylvania, Tennessee, and Virginia to participate in a pilot program to provide online purchasing of food for SNAP recipients. This brings the total number of states approved to participate in response to COVID-19 to 36 plus the District of Columbia, encompassing more than 90 percent of all SNAP participants. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.

- *New* May 18: USDA announced that Colorado, Missouri, and Wyoming were approved to
 operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families
 First Coronavirus Response Act (FFCRA), which provides assistance to families of children
 eligible for free or reduced-price meals dealing with school closures.
- *New* May 14: USDA announced that it approved Wyoming to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- *New* May 14: USDA <u>announced</u> that New Hampshire was the 20th state approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- May 12: USDA <u>announced</u> that Ohio is the 19th state approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- May 11: USDA <u>announced</u> that Texas and New Jersey were the 17th and 18th states approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- May 11: USDA <u>announced</u> that it approved Wisconsin to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- May 8: USDA announced that it approved Rhode Island to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- May 7: USDA announced that it approved New Mexico to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- May 7: USDA <u>announced</u> that New York and Pennsylvania were the 15th and 16th states approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- May 6: USDA announced that it approved Colorado to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.

- May 5: USDA <u>announced</u> that it approved Maine, North Dakota, West Virginia, and Vermont to
 participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot
 program, which was created under the 2014 Farm Bill, was previously operational in only six
 states: AL, IA, NE, NY, OR, and WA.
- May 5: USDA <u>announced</u> a major expansion of Meals to You, USDA's <u>innovative</u> <u>partnership</u> with the Baylor University Collaborative on Hunger and Poverty, McLane Global, and PepsiCo, to feed low-income kids in rural areas. The initiative will now serve nearly 5 million meals per week to rural children impacted by COVID-19-related school closures five times its original goal.
- May 4: USDA <u>announced</u> that it approved Nevada to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- May 1: USDA <u>announced</u> that it approved Minnesota to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- May 1: USDA <u>announced</u> that Delaware and Oregon were the 13th and 14th states approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- April 28: USDA <u>announced</u> that Maryland and New Mexico were the eleventh and twelfth states
 approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by
 the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of
 children eligible for free or reduced-price meals dealing with school closures.
- April 27: USDA <u>announced</u> that Kansas and Virginia were the ninth and tenth states approved to
 operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families
 First Coronavirus Response Act (FFCRA), which provides assistance to families of children
 eligible for free or reduced-price meals dealing with school closures.
- April 24: USDA announced that it approved requests from California and Connecticut and Vermont (here) to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- April 23: USDA <u>announced</u> that Wisconsin was the eighth state approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- April 22: USDA announced that Alabama was the seventh state approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.

- April 22: USDA announced that all 50 states, territories, and the District of Columbia have now been approved to provide emergency benefit allotments under SNAP, up to the maximum allowable household benefit during the COVID-19 emergency. The agency says the policy change has resulted in an increase of \$2 billion per month overall for the SNAP program.
- **April 21:** USDA <u>announced</u> that it approved requests from Kentucky, Missouri, and Texas to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- April 20: USDA announced that Arizona and Illinois have been approved to operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families First Coronavirus Response Act (FFCRA), which provides assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- April 18: In response to COVID-19, USDA <u>announced</u> that it approved a request from West Virginia to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- **April 17**: USDA <u>announced</u> the Coronavirus Food Assistance Program (CFAP), through which the agency will purchase a variety of agricultural products for distribution to food banks, in addition to other actions to protect the food supply chain.
- April 17: USDA announced that North Carolina and Massachusetts have been approved to
 operate Pandemic Electronic Benefit Transfer (EBT), a new program authorized by the Families
 First Coronavirus Response Act (FFCRA), which provides assistance to families of children
 eligible for free or reduced-price meals dealing with school closures.
- **April 17:** In response to COVID-19, USDA <u>announced</u> that it approved requests from North Carolina and the District of Columbia (DC) to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- **April 13:** USDA unveiled the COVID-19 Federal Rural Resource Guide, which is a first-of-its-kind resource for rural leaders looking for federal funding and partnership opportunities to help address this pandemic.
- **April 13:** USDA <u>announced</u> that Rhode Island is the second state approved to operate Pandemic Electronic Benefit Transfer (EBT), which is a new program, authorized by the Families First Coronavirus Act (FFCRA), to provide supplemental food purchasing assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- **April 11:** In response to COVID-19, USDA <u>announced</u> that it approved requests from Florida and Idaho to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.

- **April 9:** USDA <u>announced</u> that Michigan is the first state approved to operate Pandemic Electronic Benefit Transfer (EBT), which is a new program authorized by the Families First Coronavirus Act (FFCRA), to provide supplemental food purchasing assistance to families of children eligible for free or reduced-price meals dealing with school closures.
- **April 8**: In response to COVID-19, USDA <u>announced</u> that it approved requests from Arizona and California to participate in a pilot program to provide online purchasing of food for SNAP recipients. The pilot program, which was created under the 2014 Farm Bill, was previously operational in only six states: AL, IA, NE, NY, OR, and WA.
- April 3: USDA announced the opening of a second application window for funding under the Distance Learning and Telemedicine (DLT) grant program (details), through which an additional \$25 million is available due to the CARES Act and COVID-19. USDA expects to make up to 200 awards, between \$50,000 and \$1 million each with a required 15 percent match. Electronic applications may be submitted no later than July 13, 2020
- April 3: FNS <u>launched</u> the <u>"Meals for Kids" Site Finder</u> an online tool to help families find meals for children while schools are closed during the COVID-19 pandemic. (WHG client <u>summary</u>).
- 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 <u>announced a collaboration</u> 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 <u>flexibilities</u> 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).

DEPARTMENT OF JUSTICE

- **April 13:** The DOJ and the FTC issued a <u>joint statement</u> noting that the agencies will be closely monitoring anticompetitive behavior or collusion that disadvantages workers. This includes actions such as wage-fixing, no-poach agreements, anticompetitive non-compete agreements, and the unsanctioned exchange of employee information, including salary, wages, benefits, and compensation data.
- **April 4:** The DOJ issued a <u>letter</u> 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:** The DOJ <u>announced</u> 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 (WHG client <u>summary</u>).
- March 24: The DOJ and the Federal Trade Commission (FTC) 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 <u>foreclosure and eviction moratorium</u> (<u>press release</u>) for single family homeowners with FHA-insured mortgages for the next 60 days.

FEDERAL EMERGENCY MANAGEMENT AGENCY

- *New* May 18: FEMA released a <u>fact sheet</u> detailing steps the Supply Chain Task Force has taken to increase supply and expand domestic production of critical resources.
- *New* May 15: FEMA <u>released</u> data about the number of critical supplies, including personal protective equipment and ventilators, that have been delivered to FEMA regions across the country. A geographical breakdown is available <u>here</u>.
- May 12: FEMA released a <u>fact sheet</u> describing the conditions under which state, local, tribal, and territorial governments may receive Public Assistance (PA) Program funding for maintaining alternative care sites as "warm" sites in preparation for a second wave of COVID-19 cases.
- May 5: FEMA released a <u>fact sheet</u> detailing federal support for expanding national testing capabilities.
- May 4: FEMA <u>announced</u> \$200 million in supplemental funding allocations to local jurisdictions across the country for the <u>Emergency Food and Shelter National Board Program</u> (EFSP).
 Jurisdictions will award funding to human service organizations in early June.
- May 2: FEMA announced that on April 28, 2020, the President delegated authority to the FEMA Administrator to approve Crisis Counseling Assistance and Training (CCAT) programs related to COVID-19. The agency also announced approval of 30 states and the District of Columbia's CCAT programs, bringing the number of coronavirus-related approvals to 36.
- May 2: FEMA released a <u>fact sheet</u> with more information about the PPE shipments to nursing homes that were announced on April 30, 2020.
- May 1: FEMA released <u>FAQs</u> about assistance for tribal governments in response to the COVID-19 pandemic.

- **April 30:** FEMA released a <u>fact sheet</u> that details use of the Critical Care Decontamination SystemTM (CCDS) and notes that federal funds are available to states, tribes, territories, and localities, to produce, deploy and operate these systems at no cost.
- **April 30:** FEMA released <u>guidance</u> that builds upon the White House guidelines for Opening Up America Again by providing further reconstitution planning recommendations for state, local, tribal, territorial and private sector stakeholders.
- **April 30:** FEMA <u>announced</u> it will coordinate two 7-day supply shipments of PPE to Medicare and Medicaid-certified nursing homes across the country between May and July.
- **April 25:** FEMA <u>awarded</u> more than \$4.1 million in crisis counseling grant funding to five states. The funding is being provided through the Crisis Counseling Assistance and Training program and will be used to support residents struggling with stress and anxiety as a result of the coronavirus pandemic.
- **April 22:** FEMA released a <u>fact sheet</u> with guidance addressing how organizations should manage PPE in non-healthcare settings.
- **April 22:** FEMA released a <u>fact sheet</u> about the temporary final rule that implements the President's Memorandum, "Allocating Certain Scarce or Threatened Health and Medical Resource to Domestic Use" (WHG client <u>summary</u>).
- **April 19:** FEMA and HHS <u>announced</u> a collection of best practices for the COVID-19 response. Materials available on the <u>FEMA site</u> include those most directly relevant for emergency mangers and communities, while materials available on the <u>HHS site</u> highlight information targeted to the medical community and emergency responders.
- **April 17:** The FEMA Healthcare Resilience Task Force has released a COVID-19 <u>Hospital</u> Resource Package, which offers tools to help hospitals prepare for and respond to the pandemic.
- **April 15:** The FEMA Administrator sent a <u>letter</u> to emergency managers detailing lessons learned in the first 30 days of the COVID-19 response.
- **April 14:** The Department of Homeland Security and FEMA <u>announced</u> the funding notice for an additional \$100M in supplemental Emergency Management Performance Grant Program funds.
- **April 14:** FEMA issued a <u>press release</u> that provides an overview of the elements of the Defense Production Act (DPA) and describes how it has been applied by the administration to date. The release also clarifies that <u>Project Airbridge</u> is not authorized under the DPA.
- **April 13:** FEMA released a <u>fact sheet</u> about the agency's environmental and historic preservation compliance and conditions, which includes: details about activities the Public Assistance Program will fund; requirements for projects that have the potential to adversely affect natural, historic, and/or archaeological resources; and best practices for temporary facilities, disposal of medical waste, and decontamination activities.

- **April 13:** FEMA released a <u>fact sheet</u> about the CDC's <u>International Reagent Resource</u> which supplies resources for the surveillance and detection of respiratory pathogens to laboratories. The document lists the available resources and provides information about how to access them.
- **April 12:** FEMA <u>issued</u> a policy defining the framework and requirements for public assistance related to purchasing and distributing food for the COVID-19 public health emergency.
- **April 8:** FEMA <u>released</u> information about the actions its Supply Chain Task Force is taking to stabilize the medical supply chain.
- **April 7:** FEMA <u>released</u> information about its "Whole-of-America COVID-19 Response." The response is a "locally executed, state managed, and federally supported strategy to meet the demand for critical supplies" and is comprised of four key components: (1) preservation of medical supplies; (2) allocation of supplies to ensure they are at the right place at the right time; (3) acceleration of manufacturing and distribution; and (4) expansion of industry.
- **April 7:** FEMA <u>issued</u> a temporary final rule to distribute certain scarce PPE for domestic use, so that these materials may not be exported from the U.S. unless exempted or with the explicit approval of FEMA (WHG client summary).
- April 7: FEMA <u>announced</u> it has provided nearly \$16.7 million to the Colorado Division of Homeland Security and Emergency Management to help the state purchase PPE and other supplies for its COVID-19 response.
- **April 4:** FEMA <u>announced</u> 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 <u>fact sheet</u> outlining the requirements private non-profit (PNP) organizations must meet to be eligible to apply for funding through the <u>Public (PA) Assistance</u> Program (WHG client summary).
- March 31: FEMA <u>released</u> a FAQ about non-congregate sheltering during the COVID-19 public health emergency.
- March 31: FEMA <u>released</u> a fact sheet detailing criteria that emergency medical care activities must meet to be eligible for funding through the <u>Public Assistance (PA) Program</u>.
- March 30: FEMA and HHS <u>announced</u> 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 <u>here</u>.
- **March 29:** FEMA <u>released</u> information about how to secure 100 percent federal funding for use of the National Guard under Title 32.
- March 27: FEMA <u>announced</u> opportunities for the private sector to support the COVID-19 response, including <u>selling</u> and <u>donating</u> supplies, as well as ways for medical professionals to <u>volunteer</u>. More information about how to help is available <u>here</u>.

- March 27: FEMA sent a <u>letter</u> 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 <u>summary</u>).
- 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

- **April 29:** ACL <u>announced</u> that CMS and ASPR have launched a <u>toolkit</u> to help states navigate COVID-19 workforce challenges.
- **April 7:** ACL posted a funding opportunity for state governments to apply to receive additional funding for their ADRCs' response to the COVID-19 pandemic through the No Wrong Door System. Applications are due April 15, 2020 (WHG client <u>summary</u>).
- March 30: ACL is forecasting a grant opportunity for state governments to receive additional funding for their Aging and Disability Resource Centers (ADRCs) in response to the COVID-19 pandemic through the No Wrong Door System (WHG client summary).
- **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

- **April 17:** HRSA <u>announced</u> a coronavirus-related notice of funding opportunity (NOFO) announcement will be available soon to tribal organizations for the \$15M appropriated under the CARES Act. The funding opportunity will be posted <u>here</u>.
- March 24: HRSA <u>announced</u> it is 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 <u>summary</u>).

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

- *NEW* May 13: SAMHSA <u>announced</u> a funding opportunity for COVID-19 emergency response suicide prevention (WHG client <u>summary</u>).
- **April 27:** SAMHSA <u>issued</u> intimate partner violence and child abuse considerations during COVID-19.
- **April 20:** SAMHSA <u>awarded</u> FY 2020 Emergency COVID-19 grants totaling \$110 million today. The grants will provide up to \$2 million for state awardees and up to \$500,000 for territory and tribal awardees for 16 months. More information about the grants is available <u>here</u>.

- **April 1**: SAMHSA <u>announced</u> a funding opportunity for emergency grants to address mental and substance use disorders during COVID-19 (WHG client <u>summary</u>).
- March 31: SAMHSA <u>updated</u> 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 <u>issued</u> considerations for the care and treatment of mental and substance use disorders during the COVID-19 epidemic.
- March 20: SAMHSA <u>issued</u> considerations for outpatient mental and substance use disorder treatment settings.
- March 19: SAMHSA <u>issued</u> 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 hospitals.

SMALL BUSINESS ADMINISTRATION

Note: The latest Frequently Asked Questions (FAQs) for lenders and borrowers regarding the <u>Paycheck</u> Protection Program (PPP) is available here.

- *NEW* May 22: SBA issued an <u>interim final rule</u> to extend the limited safe harbor with respect to certification concerning need for a <u>Paycheck Protection Program (PPP)</u> loan request from May 14, 2020 to May 18, 2020 (WHG client <u>summary</u>).
- *NEW* May 18: SBA issued three interim final rules to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance regarding loan increase; extension of limited safe harbor with respect to certification concerning need for PPP; and eligibility of certain electric cooperatives (WHG client summary).
- *NEW* May 15: SBA released the <u>Paycheck Protection Program Loan Forgiveness Instructions</u> and <u>Application</u> for borrowers (WHG client <u>summary</u>).
- *NEW* May 13: SBA updated <u>Frequently Asked Questions (FAQs)</u> for lenders and borrowers regarding the Paycheck Protection Program (PPP).
- May 7: SBA issued an <u>interim final rule</u> to supplement previously posted interim final rules on the <u>Paycheck Protection Program (PPP)</u> with additional guidance on nondiscrimination obligations and additional eligibility requirements for higher education institutions (WHG client summary).
- May 1: The Small Business Administration (SBA) issued two interim final rules to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance regarding disbursements, as well as guidance on the MISSANGERICH (WHG client summary).

- **April 28:** SBA issued an <u>interim final rule</u> to supplement previously posted interim final rules (<u>85 FR 20811</u>; <u>85 FR 20817</u>; and <u>85 FR 21747</u>) on the <u>Paycheck Protection Program (PPP)</u> with additional guidance regarding promissory notes, authorizations, affiliation, and eligibility (WHG client <u>summary</u>).
- **April 23:** The SBA, in consultation with the Treasury Department, released <u>FAQs</u> regarding Paycheck Protection Program loans (WHG client <u>summary</u>).
- **April 17:** The SBA issued an <u>interim final rule</u> to supplement the first interim final rule on the Paycheck Protection Program with additional guidance regarding eligibility for individuals with self-employment income and certain businesses (WHG client <u>summary</u>).
- **April 3**: The SBA issued an <u>interim final rule</u> providing additional guidance regarding the Paycheck Protection Program (WHG client <u>summary</u>).
- **April 2**: The SBA issued Economic Injury Disaster Loan (EIDL) declarations for each State and Territory in the U.S. (WHG client <u>summary</u>).

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

• **April 9**: AHRQ announced a <u>forecasted funding opportunity</u> focused on the telehealth expansion and the role of primary care during the COVID-19 pandemic (WHG client <u>summary</u>)

THE WHITE HOUSE

- *NEW* May 19: President Trump <u>signed</u> an executive order that suspends regulations that impede economic recovery. He also directed federal agencies to think about current regulatory waivers and flexibilities that would help the economy if they were made permanent beyond the public health emergency (WHG client <u>summary</u>).
- April 28: President Trump released his <u>Blueprint for testing Plans and Rapid Response</u>
 <u>Programs</u>, intended to supplement his administration's *Opening up America Again* Guidelines and support States in establishing robust testing plans (WHG client <u>summary</u>)
- **April 24:** President Trump <u>signed</u> into law the Paycheck Protection Program and Health Care Enhancement Act, which provides \$75 billion in aid to hospitals, \$25 billion to expand federal and state coronavirus testing, \$310 billion for the Paycheck Protection Program, and \$60 billion in new disaster loans.
- **April 16:** President Trump unveiled "Guidelines for Opening Up America Again" guidance for states to reopen their economies in phases (press release; fact sheet) (WHG client summary).
- **April 3:** President Trump <u>issued</u> a "Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use" directing the Department of Homeland Security (DHS), FEMA, in consultation with HHS, to use the Defense Production Act to keep scarce medical resources within the United States for domestic use.

- April 3: During the COVID-19 task force <u>briefing</u>, 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 <u>ventilators</u>; and (2) require 3M to prioritize the production of N-95 respirators.
- March 29: President Donald Trump <u>announced</u> that the CDC was extending its <u>social distancing</u> <u>guidelines</u> 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 <u>letter</u> 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 <u>memorandum</u> 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 (<u>H.R. 6201</u>) into law
- March 18: President Trump delivered <u>remarks</u> 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 <u>classified</u> the COVID-19 outbreak as a national emergency, under the Stafford Act.
- March 11: President Trump <u>announced</u> a travel ban to Europe during a primetime news briefing to the nation.
- **March 6:** President Trump signed into law <u>H.R. 6074</u>, the \$8.3 billion emergency supplemental appropriation to address the coronavirus (COVID-19) outbreak. (WHG client <u>summary</u>).
- 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 <u>summary</u>).

CONGRESSIONAL RESPONSE

Legislation

- *New* May 22: Senate Democrats released a <u>white paper</u> outlining a series of proposals intended to expand health coverage in response to the COVID-19 pandemic (WHG client <u>summary</u>).
- *New* May 18: Sens. Bill Cassidy (R-LA) and Bob Menendez (D-NJ) recently introduced the State and Municipal Assistance for Recovery and Transition (SMART) Act (S. 3752), which would establish the Coronavirus Local Community Stabilization Fund and provide \$500 billion for FY 2020 (to remain available until expended) to state, local, and tribal governments (WHG client summary).
- May 12: House Democrats introduced The Health and Economic Recovery Omnibus Emergency Solutions Act (Heroes Act) (H.R. 6800) a \$3 trillion package to provide additional coronavirus relief (WHG client summary).
- May 5: Sens. Chris Coons (D-DE) and Reps. David Price (D-NC) and Doris Matsui (D-CA) introduced the Pandemic Response and Opportunity Through National Service Act (WHG client summary).
- **April 28:** Sen. Michael Bennet (D-CO), a member of the Senate Agriculture Committee, introduced the Food for Families in Crisis Act of 2020 a proposal that aims to expand access to food assistance through the Supplementary Nutrition Assistance Program (SNAP) (WHG client summary).
- **April 27:** Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) recently unveiled their bipartisan "Cures 2.0" <u>concept paper</u>, which outlines proposals in the following key areas: public health and pandemic preparedness, caregiver integration, patient engagement in health care decision-making, clinical trials, FDA modernization, and CMS modernization (WHG client <u>summary</u>).
- **April 24:** President Trump signed the Paycheck Protection Program and Health Care Enhancement Act into law (<u>Pub. L. 116-139</u>) (WHG client <u>summary</u>).
- April 23: The House passed passed by a roll call vote (388-5-1) the Senate-approved Paycheck Protection Program and Health Care Enhancement Act (H.R. 266) a \$484 billion relief package to provide additional coronavirus relief to small business, health care providers, and hospitals, as well as provide funding to expand COVID-19 testing capacity. The House also passed by a roll call vote (212-182) H. Res. 935, Establishing a Select Subcommittee on the Coronavirus Crisis as a select investigative subcommittee of the Committee on Oversight and Reform (WHG client summary).

- **April 21:** The Senate passed by unanimous consent a \$484 billion interim package to provide additional coronavirus relief to small businesses, health care providers, and hospitals, as well as provide funding to expand COVID-19 testing (WHG client summary).
- **April 19:** Sens. Bob Menendez and Bill Cassidy <u>announced</u> they will introduce bipartisan legislation to establish the State and Municipal Aid for Recovery and Transition (SMART) Fund a \$500 billion fund to provide COVID-19 relief to state and local governments when the Senate reconvenes (WHG client <u>summary</u>).
- **April 15:** Senate Health, Education, Labor and Pensions (HELP) Ranking Member Patty Murray (D-WA) released a <u>white paper</u> outlining Democrats' proposal to expand COVID-19 testing capacity (WHG client <u>summary</u>).
- April 9: The Senate failed to pass a measure to provide additional COVID-19 relief by unanimous consent, as each party rejected the other's proposal. Senate Majority Leader Mitch McConnell (R-KY) tried to approve \$250 billion in additional funding to the Small Business Administration's Paycheck Protection Program. Senate Democrats also called for \$250 billion for PPP, with some caveats; as well as \$100 billion in health provider relief; \$150 billion for the Coronavirus Relief Fund, which provides funds to state, tribes and localities; a 15 percent increase to the maximum SNAP benefits; and technical fixes to election assistance funding appropriated in the CARES Act (WHG client summary).
- April 8: House Speaker Nancy Pelosi (D-CA) and Senate Minority Leader Chuck Schumer released a joint statement calling for: (1) \$250 billion in assistance to small businesses, with \$125 billion channeled through community-based financial institutions; (2) \$100 billion for hospital, community health centers and health systems; and (3) \$150 billion for state and local governments; and (4) a 15 percent increase to the maximum SNAP benefit.
- **April 7:** Senate Democrats <u>unveiled</u> a proposal for a <u>"Heroes Fund"</u> to provide premium pay to frontline health care workers for potential inclusion in the forthcoming COVID-19 relief package (WHG client <u>summary</u>).
- April 7: Democratic Reps. Joe Neguse (CO), Ben Ray Luján (NM), Andy Levin (MI), and Tom Malinowski (NJ) recently introduced the Coronavirus Community Relief Act (legislative text). The bill intends to fill a funding gap in the Coronavirus Aid, Relief and Economic Security (CARES) Act, which provides relief funds to states and localities with populations of over 500,000. The Coronavirus Comunity Relief Act would provide \$250 billion in COVID-19 relief funding to local governments with a population of 500,000 or less.
- **April 4:** House Speaker Nancy Pelosi (D-CA) sent a <u>"Dear Colleague" letter</u> 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 <u>Presidential Memorandum</u> 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 <u>summary</u>).

- March 27: The House Appropriations Committee released a <u>fact sheet</u> 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 <u>introduced</u> 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 23: Sens. Chris Murphy (D-PA) and Brian Schatz (D-HI), along with Reps. Tim Ryan (D-OH) and Elisa Slotkin (D-MI), introduced the Medical Supply Chain Emergency Act of 2020 (<u>S. 3568/H.R. 6390</u>) (WHG client <u>summary</u>).
- March 22: On Sunday evening, March 22, 2020, the Senate <u>rejected</u> (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 <u>summary</u>).
- 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 (<u>H.R. 6201</u>) into law.
- March 18: The Senate passed the Families First Coronavirus Response Act (<u>H.R. 6201</u>) 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 <u>summary</u>).
- March 14: The House <u>passed</u> the Families First Coronavirus Response Act (<u>H.R. 6201</u>) by a vote of 363-40 (<u>details</u>). 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) <u>led</u> a group of Democratic Senate colleagues in introducing the Free COVID-19 Testing Act (<u>Details</u>).
- March 11: House Democrats <u>introduced</u> the Families First Coronavirus Response Act (<u>H.R.</u> 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 (<u>H.R. 6139</u>). 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 <u>summary</u>).
- **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 <u>voted</u> 91-1 to pass <u>H.R. 6074</u>, 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 <u>summary</u>).

Oversight and Other

- *NEW* May 22: House Energy and Commerce (E&C) Comittee Chairman Frank Pallone, Jr. (D-NJ), Ranking Member Greg Walden (R-OR), Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) and Oversight and Investigations Subcommittee Ranking Member Brett Guthrie (R-KY) sent a letter to White House Coronavirus Task Force Coordinator Dr. Deborah Birx urging the Trump administration to develop a national COVID-19 vaccine plan (WHG client summary).
- *NEW* May 21: The House Select Subcommittee on the Coronavirus Crisis <u>convened</u> a briefing on the impact of the COVID-19 pandemic on medical staff, first responders, grocery store workers, drivers, custodians, and other frontline workers (WHG client <u>summary</u>)
- *NEW* May 19: HHS submitted to select congressional committees a <u>report</u> of CDC's COVID-19 testing data, that was required by the Paycheck Protection Program and Health Care Enhancement Act (PPPHCEA). (WHG client <u>summary</u>).
- *NEW* May 13: The House Select Subcommittee on the Coronavirus Crisis convened a <u>briefing</u> with a bipartisan group of key experts to discuss testing, tracing, and targeted containments.
- *NEW* May 13: House Energy and Commerce Subcommittee on Health Ranking Member Michael Burgess (R-TX) sent a letter to Subcommittee Chairwoman Anna Eshoo (D-CA), requesting a hearing on how funds are being distributed to providers from Provider Relief Fund. (WHG client summary).
- May 12: The Senate Judiciary Committee convened a <u>hearing</u> to discuss liability protections for employers during the COVID-19 pandemic (WHG client summary).
- May 12: The Senate Health, Education, Labor and Pensions Committee convened a hearing to examine the federal government's response to the COVID-19 pandemic and discuss challenges and strategies to safely reopen the country (WHG client <u>summary</u>).
- May 7: The Senate Health, Education, Labor & Pensions (HELP) Committee convened a hearing to discuss the National Institutes of Health (NIH) and the Biomedical Advanced

- Research and Development Authority (BARDA) initiatives to accelerate access to innovative diagnostic testing technology for COVID-19 (WHG client <u>summary</u>).
- April 30: House Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ), Health Subcommittee Chairwoman Anna Eshoo (D-CA) and Oversight and Investigations Chairwoman Diana DeGette (D-CO) sent a letter to Health and Human Services (HHS) Secretary Alex Azar, urging the Department to develop a national COVID-19 contact tracing strategy.
- April 29: House Oversight Subcommittee on Economic and Consumer Policy Chairman Raja Krishnamoorthi (D-IL) <u>sent</u> a letter to the Food and Drug Administration (FDA), requesting the agency comply with the Subcommittee's investigation of its policies governing coronavirus serological testing (WHG client <u>summary</u>).
- **April 29:** House Speaker Nancy Pelosi <u>appointed</u> Members to serve on the bipartisan House Select Committee on the Coronavirus Crisis, which will conduct oversight of the federal response to the coronavirus crisis.
- **April 27:** The House Democrats' Task Force on Aging and Families unveiled a <u>set of principles</u> for protecting older Americans amid COVID-19 to guide future relief legislation (WHG client <u>summary</u>).
- **April 24:** CRS published a <u>brief report</u> on current COVID-19 public health surveillance systems, recent legislative and executive actions to address public health reporting, and policy consideration to help support the nation's response as well as local-level public health decision-making.
- April 23: CRS published a brief report on key COVID-19 testing issues.
- **April 20:** Senate Finance Committee Ranking Member Ron Wyden (D-OR) <u>released</u> a <u>letter</u> from the Department of Labor (DOL) clarifying <u>guidance</u> regarding the Pandemic Unemployment Assistance (PUA) Program (WHG client <u>summary</u>).
- **April 20:** CRS published a <u>brief report</u> on the effect of the COVID-19 pandemic on organ donation and transplantation.
- April 20: CRS published a <u>snapshot</u> of the domestic public health response to COVID-19, as of April 16, 2020, including actions taken by the White House; HHS, CDC, FDA, and FEMA; and Congress.
- **April 20:** House Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ) <u>sent</u> a <u>letter</u> to Coronavirus Task Force Coordinator Dr. Deborah Birx, requesting information on the Trump administration's plans to expand testing and prepare for the easing of social distance guidelines (WHG client <u>summary</u>).
- April 20: House Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ), Health Subcommittee Chairwoman Anna G. Eshoo (D-CA) and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) sent a letter to Health and Human Services (HHS) Secretary Alex Azar and Federal Emergency Management Agency (FEMA) Administrator Peter

Gaynor, demanding detailed information on the acquisition and distribution of COVID-19 medical supplies (WHG client <u>summary</u>).

- April 17: Senate Finance Committee Chairman Chuck Grassley (R-IA) sent a letter to HHS Secretary Alex Azar and CMS Administrator Seema Verma, requesting detailed information on CMS plans to update its guidance or training requirements on infection control procedures; the planned use of the \$100 billion Provider Relief Refund, including a detailed account of the \$30 billion that has been dispersed; the timeline for state or local authorities to notify CDC about a positive COVID-19 case, outbreak, or related death and for CDC to relay that information to HHS and CMS; and other details about the federal response in nursing homes.
- **April 17:** Senate Finance Committee Ranking Member Ron Wyden (D-OR) and Senate Aging Committee Ranking Member Bob Casey (D-PA) issued a <u>joint statement</u> condemning the Trump administration for not releasing the list of nursing facilities that documented cases of COVID-19. They had requested the information in a <u>letter</u> to CMS and CDC sent on April 2.
- April 17: House Ways and Means Committee Chairman Richard Neal (D-MA) <u>urged CMS</u>
 to require nursing facilities to inform the public when residents or staff members test positive, in
 addition to the actions that the facility is taking to treat infected residents and protect other
 individuals. He also encourages states to the release the names of facilities that have confirmed
 positive cases.
- **April 16:** Senate Finance Committee Ranking Member Ron Wyden (D-OR) and 11 other Democratic colleagues <u>sent</u> a <u>letter</u> to Health and Human Services (HHS) Secretary Alex Azar, urging the Department to prioritize transparency, equity, and urgency when distributing the remaining \$70 billion in the <u>Provider Relief Fund</u> (WHG client <u>summary</u>).
- **April 14:** House Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) and Oversight and Investigations Subcommittee Chair Diana DeGette (D-CO) <u>sent</u> a <u>letter</u> urging Health and Human Services (HHS) Secretary Alex Azar to ensure the work of the HHS Office of Inspector General (OIG) remains independent and to cooperate with all OIG evaluations, audits, and investigations (WHG client <u>summary</u>).
- April 13: House Ways and Means Chairman Richard E. Neal (D-MA), Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ), Education and Labor Chairman Bobby Scott (D-VA), along with Senate Finance Committee Ranking Member Ron Wyden (D-OR) and Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Patty Murray (D-WA) sent a letter to Health and Human Services Secretary Alex Azar, Treasury Secretary Steven Mnuchin, and Labor Secretary Eugene Scalia, urging the Trump administration to establish a new Special Enrollment Period (SEP) and increase awareness of the existing SEP for individuals who lose their employer-based health coverage (WHG client summary).
- April 10: House Majority Leader Steny Hoyer (D-MD) recently <u>sent</u> a letter to the Chair and Vice Chair of the National Governors Association, Gov. Larry Hogan (R-MD) and Gov. Andrew Cuomo (D-NY), urging them to direct state governors to collect demographic data on racial disparities and the coronavirus.
- **April 8:** House Oversight and Reform Committee Chairwoman Carolyn Maloney (D-NY) released a new report compiled by the Department of Health and Human Services (HHS) (at the request of the Committee) detailing the distribution of personal protective equipment (PPE) and

- supplies from the Strategic National Stockpile to states (as of April 6, 2020) (WHG client summary).
- April 8: Sens. Jeanne Shaheen (D-NH) and Bill Cassidy (R-LA) <u>led</u> a bipartisan <u>letter</u> to HHS
 Secretary Alex Azar and CMS Administrator Seema Verma, calling for more flexibility on
 interest rates and repayment of Medicare's accelerated advance payments (WHG client
 <u>summary</u>).
- 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 <u>Delaware</u>, the <u>District of Columbia</u>, <u>Maryland</u>, <u>Pennsylvania</u>, <u>Virginia</u>, and <u>West Virginia</u>.
- **April 2:** House Speaker Nancy Pelosi (D-CA) <u>announced</u> 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 <u>sent</u> 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) <u>led</u> 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 <u>Legal Sidebar</u> 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 <u>letter</u> 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 <u>summary</u> 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 <u>summary</u> of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (<u>H.R. 6074</u>), 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) <u>sent</u> 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 <u>warning</u> issued by the Food and Drug Administration (FDA) against using "unauthorized fraudulent" at-home test kits.
- March 21: House Oversight Committee Democratic leaders <u>sent</u> 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 <u>sent</u> 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) <u>led</u> 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 <u>summary</u>).
- March 17: House E&C Committee Chairman Frank Pallone, Jr. (D-NJ) and other Democratic committee leaders <u>sent</u> 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 "<u>Economic and Community Services Proposal</u>," 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 <u>brief report</u> discussing the potential challenges of COVID-19 to the United States' blood supply. (WHG client <u>summary</u>).

- March 9: The Congressional Research Service (CRS) released a <u>summary</u> 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) <u>sent</u> a <u>letter</u> 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 <u>summary</u>).

FUNDING

WHG has developed funding charts relevant to different stakeholders eligible for COVID-19 stimulus funding opportunities. The complete and regularly updated charts are available at the following links for Providers, States & Local governments, and Employers.

While the charts include more detailed information on the funding opportunities, including eligibility and implementation information, we include below brief highlights on currently open opportunities on which stakeholders may act now.

Open Funding Opportunities

Funding Initiative (Authorizing	Funding	Agency	Actionable Dates
legislation)	Amount		
COVID-19 Telehealth Program	\$200M	FCC	Application opened April 13, 2020;
(<u>funding notice</u>) (Phase III)			funding available until exhausted
New Emergency Grants to	\$40M	SAMHSA	Application deadline is May 22,
Address Mental and Substance Use			2020
Disorders During COVID-19 (<u>FG-</u>			
<u>20-007</u>) (Phase III)			
Supporting Tribal Public Health	\$40M	CDC	Application deadline is May 31,
Capacity in Coronavirus			2020
Preparedness and Response (CDC-			
<u>RFA-OT20-2004</u>) (Phase I)			
New Novel, High-Impact Studies	\$5M	AHRQ	Application deadline is June 15,
Evaluating Health System and			2020
Healthcare Professional			
Responsiveness to COVID-19			
(<u>RFA-HS-20-003</u>)			