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

March 2021 Edition

In response to the novel coronavirus (COVID-19) pandemic, U.S. government agencies have continued the frequent release of fact sheets and guidance documents for health care and public stakeholders. To help navigate the outpouring of information, the Wynne Health Group has maintained the attached and newly updated catalogue, intended to capture and organize the full array of relevant guidance for health care providers, insurers, state governments, public health agencies, and other stakeholders, as well as reflect the status of major actions by the White House and Congress, and pertinent funding opportunities. Using the hyperlinks below, you can jump to each section of the full compendium.

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

Benefits and Coverage

- *NEW* March 23: CMS <u>announced</u> it is extending the ongoing special enrollment period (SEP) for an additional three months (i.e., until August 15, 2021). (WHG client summary).
- *NEW* March 15: CMS released an updated <u>toolkit</u> on Coverage and Reimbursement of Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program to reflect some of the changes made in the recently American Rescue Plan Act of 2021 (ARPA) (P.L. 117-2). (WHG client <u>summary</u>).
- *NEW* March 15: CMS <u>announced</u> an increase to the Medicare payment rates for COVID-19 vaccine administration. (WHG client <u>summary</u>).
- *NEW* March 12: CMS released a new <u>fact sheet</u> detailing the changes to financial assistance eligibility for Marketplace health plan enrollees that were effectuated through signing of the American Rescue Plan Act. The changes lower premiums for most people who are enrolled in health insurance through the exchanges. Increased premium tax credits will be available starting April 1, 2020 and CMS notes that current enrollees will need to submit a new application to receive increased assistance.
- *NEW* March 4: CMS <u>announced</u> that more than 206,000 individuals have signed up for Affordable Care Act coverage in the first two weeks of the Coronavirus-related special enrollment period which runs through May 15.

- **November 9:** CMS <u>announced</u> that Medicare now offers coverage of bamlanivimab (a monoclonal antibody therapy) used to treat COVID-19 at no cost sharing for the duration of the public health emergency. (WHG client <u>summary</u>).
- October 28: CMS released its fourth COVID-19 <u>interim final rule</u> (IFC), which includes several provisions to prepare for coverage of forthcoming vaccines and treatments for the disease (<u>press release</u>; <u>fact sheet</u>). (WHG client <u>summary</u>).
- **August 4:** CMS <u>announced</u> new guidance (<u>here</u>) stating it will temporarily be exercising enforcement discretion to allow health plan issuers in the individual and small group markets to offer premium reductions for one or more months for 2020 coverage (WHG client <u>summary</u>).
- 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 guidance to help Medicare Advantage and Part D plans respond to the coronavirus (WHG client <u>summary</u>).

Infection Control and Prevention

- *NEW* March 26: CMS is resuming hospital survey activities following 30-day restrictions.
- *NEW* March 15: CMS released a graphic to help further explain its <u>updated guidance</u> on nursing home visitation.
- *NEW* March 10: CMS updated its <u>guidance</u>, in partnership with the CDC, for safe visitation in nursing homes during the COVID-19 public health emergency (<u>press release</u>; <u>fact sheet</u>). The changes reflect the impact of vaccinations on COVID-19 infections in nursing homes (WHG client summary).
- **February 10:** CMS issued <u>new guidance</u> to state survey agencies for visitation at intermediate care facilities for individuals with intellectual disabilities and psychiatric residential treatment facilities during the COVID-19 public health emergency.

- **January 20:** CMS released a <u>memorandum</u> to state survey agencies clarifying survey priorities for hospitals during the COVID-19 public health emergency.
- **December 30:** CMS released a <u>memorandum</u> to state survey agencies that revises the COVID-19 Focused Infection Control Survey Tool for Acute and Continuing Care.
- **December 17:** CMS released a <u>memorandum</u> to state survey agencies providing guidance on COVID-19 infection control for psychiatric and intermediate care facilities for individuals with intellectual disabilities (ICFs/IID).
- October 30: CMS <u>announced</u> the launch of the <u>Nursing Home Resource Center</u>, which provides information, guidance, and data for nursing homes combatting the COVID-19 pandemic.
- **September 30:** The Centers for Medicare & Medicare Services (CMS) <u>announced</u> that it is relaxing its nursing home testing requirements (WHG client <u>summary</u>).
- **September 17:** CMS <u>released</u> new guidance for safe visitation in nursing homes during the COVID-19 public health emergency (WHG client <u>summary</u>).
- **September 16:** An independent commission convened by the Centers for Medicare & Medicaid Services (CMS) released its findings and recommendations on ensuring safety and quality in nursing homes during the COVID-19 response (<u>press release</u>; <u>full report</u>). (WHG client summary).
- August 26: CMS released a <u>memorandum</u> to state survey agencies providing additional guidance on its August 25 interim final rule imposing new requirements on long-term care facilities, hospitals, laboratories, and other facilities.
- August 25: CMS <u>released</u> an <u>interim final rule with comment period</u> (IFC) specifying new requirements for long-term care facilities, hospitals, laboratories, and other facilities in response to the COVID-19 public health emergency (PHE) (WHG client <u>summary</u>).
- **August 17:** CMS <u>announced</u> it will resume routine inspections of all providers and suppliers, along with updated enforcement guidance to states regarding these inspections (<u>memorandum</u>). The agency also released an updated nursing home toolkit (WHG client <u>summary</u>).
- **July 22:** CMS <u>announced</u> a new set of actions to support nursing homes and prevent further outbreaks during the COVID-19 pandemic. Details on the components of this latest initiative follow (WHG client <u>summary</u>).
- July 15: CMS updated its toolkit for states to mitigate COVID-19 in nursing homes
- July 13: CMS <u>announced</u> additional resources distributed to nursing homes in COVID-19 hotspot areas, including a plan to deploy Quality Improvement Organization (QIOs) for immediate assistance.
- **June 26:** CMS <u>issued</u> guidance for Phase II visitation for patients who are COVID-19 negative, which includes discretionary visitation under limited circumstances.

- **June 1:** CMS <u>announced</u> new <u>enforcement actions</u> it will take against nursing homes in an effort to address the spread of COVID-19.
- 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>).
- 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 <u>summary</u>).
- 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 summary).
- **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 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 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 **nursing homes** to significantly restrict visitors and nonessential personnel, as well as restrict communal activities inside nursing homes.
- March 10: CMS issued memoranda to dialysis facilities (here) and home health providers (here) on screening and containment strategies for patients, visitors, and staff. (WHG client summary).
- March 9: CMS published <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 summary).
- March 4: CMS issued a memo to State Survey Agencies and Accrediting Organizations indicating that, effective immediately, all non-emergency inspection activities are suspended so that inspectors can turn their focus to the most serious health and safety threats, including abuse and COVID-19 and other infectious disease control. (WHG client summary).

Data

- *NEW* March 24: CMS released an updated data snapshot detailing the impact of COVID-19 on Medicare beneficiaries. (WHG client summary).
- **January 15:** CMS <u>released</u> its monthly update detailing the impact of COVID-19 on Medicare beneficiaries. The agency also <u>released</u> new data from the Medicare Current Beneficiary Survey about beneficiaries' experiences.
- October 9: CMS <u>released</u> its monthly update detailing the impact of COVID-19 on Medicare beneficiaries.
- **September 11:** CMS <u>released</u> its monthly update detailing the impact of COVID-19 on Medicare beneficiaries.

- **August 14:** CMS <u>released</u> its monthly update detailing the impact of COVID-19 on Medicare beneficiaries.
- **July 17:** CMS <u>released</u> its first monthly update to its report detailing the impact of COVID-19 on Medicare beneficiaries (WHG <u>client summary</u>).
- **June 11:** CMS released new data detailing the cumulative impact of COVID-19 on Medicare beneficiaries (data; FAQ; CMS Administrator Seema Verma blog post) (WHG client summary).

Waivers and other Emergency Flexibilities

- *NEW* March 1: CMS <u>announced</u> it is making \$2.3 million available to support current Navigator grantees in Federally-facilitated Marketplace states. The funding is being made available to improve enrollment efforts for the Special Enrollment Period opened in response to the COVID-19 pandemic.
- **January 8:** CMS <u>released</u> surveyor guidance for new and modified CLIA requirements related to SARSCoV-2 test result reporting.
- **December 30:** CMS released a <u>memorandum</u> to state survey agencies permitting ASCs to keep medically stable patients for observation during the public health emergency.
- **June 26:** CMS <u>announced</u> it is ending the emergency waiver that excused nursing homes from reporting staffing data through the Payroll-Based Journal (PBJ) system (WHG client <u>summary</u>).
- **June 3:** CMS published a <u>blog</u> outlining new payment flexibilities for CMS Innovation Center models in light of the COVID-19 pandemic.
- 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

- **February 22:** CMS approved a disaster relief SPA requested by <u>Louisiana</u>.
- **February 22:** CMS approved a disaster relief SPA requested by Connecticut.
- **February 12:** CMS approved a disaster relief SPA requested by Massachusetts.
- **January 19:** CMS approved a disaster relief SPA requested by North Dakota.
- January 12: CMS approved additional 1135 waiver flexibilities requested by Minnesota.
- **December 23:** CMS approved additional 1135 waiver flexibilities requested by <u>Massachusetts</u> and Alaska.
- December 18: CMS approved additional 1135 waiver flexibilities requested by <u>Kentucky</u> and Nevada.
- **December 9:** CMS approved additional 1135 waiver flexibilities requested by <u>Oregon</u>.

- **December 2:** CMS approved additional 1135 waiver flexibilities requested by <u>Oregon</u>.
- November 25: CMS approved additional 1135 waiver flexibilities requested by <u>Texas</u>.
- November 5: CMS approved additional 1135 waiver flexibilities requested by Montana.
- November 2: CMS approved additional 1135 waiver flexibilities requested by Minnesota.
- October 6: CMS approved additional 1135 waiver flexibilities requested by New York and Pennsylvania.
- **September 30:** CMS approved additional 1135 waiver flexibilities requested by <u>Texas</u>.
- **September 21:** CMS approved additional 1135 waiver flexibilities requested by Michigan.
- **September 16:** CMS approved additional 1135 waiver flexibilities requested by <u>Oregon</u>.
- **August 31:** CMS approved additional 1135 waiver flexibilities requested by <u>South Dakota</u> and <u>Maryland</u>.
- August 28: CMS approved additional 1135 waiver flexibilities requested by North Carolina.
- August 21: CMS approved additional 1135 waiver flexibilities requested by Connecticut.
- August 20: CMS approved additional 1135 waiver flexibilities requested by Oregon.
- August 19: CMS approved additional 1135 waiver flexibilities requested by <u>California</u>, <u>Alaska</u>, and New York.
- August 18: CMS approved additional 1135 waiver flexibilities requested by Tennessee.
- August 7: CMS approved additional 1135 waiver flexibilities requested by Iowa and Louisiana.
- August 4: CMS approved additional 1135 waiver flexibilities requested by New York.
- July 31: CMS approved additional 1135 waiver flexibilities requested by Maryland.
- **July 30:** CMS approved additional 1135 waiver flexibilities requested by <u>Missouri</u>.
- July 29: CMS approved additional 1135 waiver flexibilities requested by Pennsylvania.
- July 24: CMS approved additional 1135 waiver flexibilities requested by <u>Wyoming</u>.
- **July 23:** CMS approved additional 1135 waiver flexibilities requested by <u>Texas</u>.
- July 9: CMS approved additional 1135 waiver flexibilities requested by Arizona.
- July 7: CMS approved additional 1135 waiver flexibilities requested by South Carolina.

- **July 1:** CMS approved additional 1135 waiver flexibilities requested by New Mexico.
- **June 26:** CMS approved additional 1135 waiver flexibilities requested by New Hampshire.
- **June 23:** CMS approved additional 1135 waiver flexibilities requested by Montana.
- June 22: CMS approved additional 1135 waiver flexibilities requested by New York.
- **June 18:** CMS approved additional 1135 waiver flexibilities requested by Washington.
- **June 17:** CMS approved additional 1135 waiver flexibilities requested by Connecticut.
- **June 16:** CMS approved additional 1135 waiver flexibilities requested by <u>Massachusetts</u> and <u>Colorado</u>.
- **June 15:** CMS approved additional 1135 waiver flexibilities requested by <u>Alaska</u>, <u>New York</u>, and <u>South Carolina</u>.
- **June 12:** CMS approved additional 1135 waiver flexibilities requested by the state of <u>Utah</u> in its initial request, and approved a second and third round of requests for the State of <u>New Jersey</u>.
- **June 9:** CMS approved additional rounds of requested 1135 waiver flexibilities for the states of Tennessee, Delaware, West Virginia, and Pennsylvania.
- **June 8:** CMS approved a second round of requested 1135 waiver flexibilities for the state of Oklahoma.
- **June 5:** CMS approved a second round of requested 1135 waiver flexibilities for the state of Wisconsin.
- **June 3:** CMS approved an additional set of requested 1135 waiver flexibilities for the state of <u>Alaska</u>.
- **June 1:** CMS approved a second round of requested 1135 waiver flexibilities for the state of Mississippi and an eighth request from the state of Arizona.
- May 29: CMS approved a second round of requested 1135 waiver flexibilities for the state of Alaska.
- May 28: CMS approved an initial round of requested 1135 waiver flexibilities for the state of
 Ohio; a second and third round of requests for the state of Vermont; and a third round of requests for the state of Maine.
- May 26: CMS approved a second round of requested 1135 waiver flexibilities for the state of New Hampshire.
- 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.

- May 19: CMS approved an 1135 waiver for the state of Virginia.
- May 18: CMS approved a second, third, and fourth round of requested 1135 waiver flexibilities for the state of Rhode Island.
- May 15: CMS approved an 1135 waiver for the state of <u>Alaska</u>.
- May 14: CMS approved an 1135 waiver for the state of Missouri.
- May 14: CMS approved a second round of requested 1135 waiver flexibilities for the state of Georgia.
- 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 Arizona, Washington, Maryland and New York.
- May 5: CMS approved a second round of requested 1135 waiver flexibilities from each of the states of Arkansas and Iowa.
- April 22: CMS approved an 1135 waiver for the state of Ohio.
- April 20: CMS approved an 1135 waiver for the state of Wisconsin.
- **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>, Nevada, Michigan, and the District of Columbia, 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 Montana, Texas, Vermont, and West Virginia, bringing the total number approved to 38. All waivers are available here.
- 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.

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 <u>summary</u>).

Telehealth & Provider Enrollment

- *NEW* March 23: The CMS From Coverage to Care (C2C) program <u>released</u> a set of resources to aid providers and patients as telehealth systems continue to be implemented in response to the COVID-19 pandemic. (WHG client <u>summary</u>).
- **January 7:** CMS <u>updated</u> the Medicare frequently asked questions (FAQs) on Medicare fee-for-service billing.

- **September 25:** CMS <u>released</u> a new <u>toolkit</u> aimed at streamlining the process for receiving Clinical Laboratory Improvement Amendments (CLIA) certification for laboratories who want to administer COVID-19 tests.
- 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; 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

• **February 25:** CMS announced it is applying the MIPS Extreme and Uncontrollable Circumstances Policy for the 2020 Performance Period due to COVID-19. The agency also stated that it had reopened the MIPS EUC application for individual MIPS eligible clinicians, groups, virtual groups, and Alternative Payment Model (APM) Entities through March 31, 2021 at 8 p.m. ET.

- **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 <u>summary</u>).
- **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 <u>Medicare Advantage (MA) risk adjustment</u>, and the other to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) <u>Competitive Bidding Program</u>. (WHG client summary).

Coding and Reimbursement

- **September 18:** CMS <u>released</u> details on the payment and codes for COVID-19 viral testing in Medicare, Medicaid and the uninsured, and private insurance.
- **July 15:** CMS <u>updated</u> its COVID-19 frequently asked questions (FAQs) on Medicare fee-for-service billing.
- May 27: CMS updated its <u>FAQ document</u> on fee-for-service billing guidance for Medicare providers.
- 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 <u>summary</u>).
- 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 <u>summary</u>).

Medicaid & CHIP

- June 30: CMS issued <u>additional Frequently Asked Questions (FAQs)</u> to aid state Medicaid and CHIP agencies in their response to the COVID-19 pandemic. The new FAQs cover a variety of Medicaid and CHIP topics, including: eligibility and Enrollment; notice and fair hearings; optional COVID-testing group FAQs; premiums and cost sharing; benefits; Non-Emergency Medical Transportation (NEMT); Information Technology; and financing. (WHG client <u>summary</u>).
- **June 2:** CMS released <u>guidance</u> on implementation of the new, optional Medicaid eligibility group for uninsured individuals created under the Families First Coronavirus Response Act (FFCRA). (WHG client summary).
- 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.

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 (details).
- 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 summary).

FOOD & DRUG ADMINISTRATION

Treatments and Vaccines

- *NEW* March 24: The FDA <u>published</u> a new webpage to provide information on the authorized COVID-19 vaccines.
- *NEW* February 27: The FDA <u>issued</u> emergency use authorization (EUA) for the single-dose Johnson & Johnson COVID-19 vaccine for individuals 18 years and older.
- **February 22:** The FDA <u>updated</u> guidance on emergency use authorization for vaccines to prevent COVID-19 to provide recommendations on how to address COVID-19 variants.
- **February 22:** The FDA <u>issued</u> new guidance entitled the development of monoclonal antibody products targeting SARS-CoV-2, including addressing the impact of emerging variants, and <u>revised</u> existing guidance on developing drugs and biological products for the treatment or prevention of COVID-19.
- **February 9:** The FDA <u>issued</u> emergency use authorization (EUA) for the combination of bamlanivimab and etesevimab (monoclonal antibodies) for the treatment of mild to moderate COVID-19 in adults and pediatric patients at least 12 years old who are high risk for progressing to severe COVID-19 (WHG client <u>summary</u>).
- **February 4:** The FDA <u>amended</u> the <u>emergency use authorization</u> (EUA) for the use of convalescent plasma as a COVID-19 treatment to high titer plasma use early in the disease course. (WHG client <u>summary</u>).

- **February 4:** The FDA <u>announced</u> an upcoming Vaccines and Related Biological Products Advisory Committee (VRPAC) meeting on February 26 to examine the Janssen Biotech Inc. EUA request for its COVID-19 vaccine candidate.
- **January 15:** The FDA issued three new guidance documents to address <u>monoclonal antibody</u> <u>therapeutics</u>, <u>coagulation systems</u>, and <u>bioequivalence studies</u> during the COVID-19 pandemic.
- **January 13:** The FDA <u>released</u> a <u>report</u> on the agency's COVID-19 Pandemic Recovery and Preparedness Plan (PREPP) Initiative, which reflects the FDA's accomplishments to-date and potential prospective actions moving forward.
- **January 4:** The FDA <u>announced</u> that providers administrating authorized COVID-19 vaccines should not change the authorized dosing or schedules.
- **December 18:** The FDA <u>issued</u> emergency use authorization (EUA) for the Moderna COVID-19 vaccine. The vaccine is approved for use in individuals 18 years of age and older.
- **December 11**: The FDA <u>issued</u> emergency use authorization (EUA) for the first COVID-19 vaccine, the Pfizer-BioNTech COVID-19 vaccine, for individuals 16 years of age and older.
- December 8: The FDA <u>posted</u> background material for the upcoming Vaccines and Related Biological Products Advisory Committee (VRBPAC) public meeting to review the Pfizer-BioNTech COVID-19 Vaccine.
- **December 1**: The FDA <u>announced</u> it has scheduled a meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) on December 17 to examine the Moderna COVID-19 vaccine candidate.
- **November 21**: The FDA <u>issued</u> emergency use authorization (EUA) for casirivimab and imdevimab, administered together by intravenous (IV) infusion, for the treatment of mild to moderate COVID-19 in adults and pediatric patients.
- **November 20**: The FDA <u>announced</u> it has scheduled a meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) on December 10 to examine the Pfizer-BioNTech COVID-19 vaccine candidate.
- **November 19:** The FDA <u>issued</u> emergency use authorization (EUA) for baricitinib, in combination with remdesivir, for the treatment of suspected for confirmed COVID-19 in hospitalized adults and pediatric patients two year of age or older requiring supplemental oxygen.
- **November 9:** The FDA <u>issued</u> an emergency use authorization (EUA) for Eli Lilly's investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.
- October 22: The FDA <u>approved</u> remdesivir as the first treatment for COVID-19. The drug is approved for use in adults and pediatric patients 12 years of age and older and weighing at least 50 kilograms for the treatment of COVID-19 requiring hospitalization.

- October 20: The Director of the FDA's Centers for Biologics Evaluation and Research <u>published</u> a blog detailing the FDA's Vaccines and Related Biological Products Advisory Committee's role in advising the agency on COVID-19 vaccines.
- October 6: The FDA <u>issued</u> guidance on emergency use authorization (EUA) for COVID-19 vaccines (WHG client <u>summary</u>).
- **September 28:** The FDA <u>issued</u> final guidance on assessing COVID-19 related symptoms in outpatient adults and adolescent subjects in clinical trials of drugs and biological products for COVID-19 prevention or treatment (WHG client <u>summary</u>).
- **September 2:** The FDA <u>updated</u> its guidance on investigational COVID-19 convalescent plasma to provide additional information related to the recently issued emergency use authorization (EUA).
- **August 28:** The FDA <u>updated</u> the emergency use authorization (EUA) for remdesivir to include treatment of all hospitalized adult and pediatric patients with suspected or laboratory confirmed COVID-19 (WHG client summary).
- **August 24:** The FDA <u>issued</u> an <u>emergency use authorization (EUA)</u> for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients (WHG client summary).
- **July 30:** The FDA <u>updated</u> its FAQs on the Emergency Use Authorization (EUA) for remdesivir among certain hospitalized COVID-19 patients.
- **July 13:** The FDA <u>announced</u> that scientists from the agency have identified specific areas on the 'spike protein' of SARS-CoV-2 that are key to triggering strong protective antibody responses in rabbits, which may assist in vaccine development.
- **June 30:** The FDA <u>issued</u> guidance to assist sponsors with the development and licensure of COVID-19 vaccines, which describes the data needed to ensure safety and efficacy of the vaccine candidate (WHG client summary)
- June 15: The FDA <u>announced</u> that co-administration of remdesivir and chloroquine phosphate or hydroxychloroquine phosphate is not recommended due to a potential drug interaction that may reduce effectiveness.
- **June 15:** The FDA <u>revoked</u> the Emergency Use Authorization (EUA) for hydroxychloroquine sulfate (HCQ) and chloroquine sulfate (CQ) as treatments for COVID-19 due to new evidence that demonstrates that the treatments may not be effective and other serious side effects (WHG client <u>summary</u>).
- **June 1:** The FDA <u>issued</u> a Consumer Update to help the public understand the regulatory terminology of potential preventions and treatments for COVID-19.
- **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 summary).
- **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 summary)
- **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 summary)
- **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 COVID-19 (WHG client summary).
- 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)

- **November 24**: The FDA <u>published</u> a new page entitled "Face Masks, Including Surgical Masks, and Respirators for COVID-19" in order to answer frequently asked questions (FAQs).
- **June 7:** The FDA <u>issued</u> revised Emergency Use Authorizations (EUAs) to specify which respirators are appropriate for decontamination and reuse (WHG client <u>summary</u>)
- **June 1:** The FDA <u>updated</u> its guidance on alcohol-based hand sanitizers to provide additional clarity on the manufacturing and compounding process and help ensure that harmful levels of impurities are not present.
- May 28: The FDA <u>issued</u> an Emergency Use Authorization (EUA) for the Stryker Sustainability Solutions (SSS) VHP N95 Respirator Decontamination System (RDS), which uses vapor hydrogen peroxide to decontaminate compatible N95 respirators
- May 26: The FDA <u>issued</u> an Emergency Use Authorization (EUA) for the use of certain gowns, shoe covers, and other apparel for use by health care providers as personal protective equipment (PPE) in health care settings in accordance with CDC recommendations.
- **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 <u>summary</u>)
- **March 24:** FDA <u>provided</u> instructions to manufacturers to import personal protective equipment (PPE) and other devices (WHG client <u>summary</u>)
- **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 summary).

- 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 summary).
- 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* March 19: The FDA <u>issued</u> an emergency use authorization (EUA) for the first machine learning-based COVID-19 non-diagnostic screening device that identifies certain biomarkers that are indicative of SARS-CoV-2 infection.
- *NEW* March 5: The FDA <u>issued</u> emergency use authorization (EUA) for the T-Detect COVID test, which will aid in identifying individuals with recent or prior SARS-CoV-2 infection.
- *NEW* March 5: The FDA <u>issued</u> EUA for the first molecular non-prescription, at-home COVID-19 test.
- *NEW* March 1: The FDA <u>issued</u> EUA for the Quidel QuickVue At-Home COVID-19 test, a antigen test that can be rapidly collected and tested at home.
- **February 22:** The FDA <u>issued</u> new guidance for test developers on policy for evaluating impact of viral mutations on COVID-19 tests.
- **December 9:** The FDA <u>issued</u> an emergency use authorization (EUA) for the first direct-to-consumer COVID-18 test system.
- **December 4:** The FDA <u>issued</u> the first emergency use authorization (EUA) for a diagnostic test for at home collection of patient sample to detect both COVID-19 and influenza A and B.
- **November 17:** The FDA <u>issued</u> an emergency use authorization (EUA) the first COVID-19 test for self-testing at home.
- **November 6:** The FDA <u>authorized</u> the first serology test that detects neutralizing antibodies from recent or prior COVID-19 infection. All prior serology tests were authorized to test for the presence of biding antibodies.
- **September 23:** The FDA <u>issued</u> the first emergency use authorization (EUA) for a COVID-19 serology (antibody) point-of-care test. This will allow fingerstick blood samples to be tested in point-of-care settings, such as doctor's office, urgent care centers, and emergency rooms.
- August 26: The FDA <u>issued</u> an emergency use authorization (EUA) for the first COVID-19 antigen test where results can be read directly from the testing card, eliminating the need to use an analyzer (press release) (WHG client summary).

- **July 30:** The FDA <u>posted</u> frequently asked questions (FAQs) for patient and consumers about COVID-19 antibody testing.
- **July 29:** The Food and Drug Administration (FDA) posted a <u>new template</u> for at-home and overthe-counter COVID-19 diagnostic tests for use in non-lab settings (<u>press release</u>) (WHG client <u>summary</u>).
- **July 24:** The FDA <u>issued</u> the first Emergency Use Authorization (EUA) for a diagnostic test for people without known of suspected COVID-19 infection, which will allow for pooled testing.
- **July 18:** The FDA <u>issued</u> the first Emergency Use Authorization (EUA) for sample pooling in diagnostic testing. This EUA allows for up to four samples to be tested at the same time.
- **July 15:** The FDA <u>updated</u> its FAQs on testing for COVID-19 to include a list of laboratories that have been removed due to significant problems identified with the lab-developed diagnostic test.
- **July 6:** The FDA <u>issued</u> the second Emergency Use Authorization (EUA) for a COVID-19 point of care antigen test, which quickly detects fragments of proteins found on or within the virus.
- **July 6:** The FDA <u>issued</u> the third Emergency Use Authorization (EUA) for a diagnostic test that detects COVID-19 and different variations of the viruses that cause the flu.
- **June 18:** The FDA <u>announced</u> its participation in the COVID-19 Diagnostics Evidence Accelerator, which aims to advance the development of diagnostics through the collection and utilization of real-world data.
- **June 16:** The FDA <u>announced</u> updated <u>Emergency Use Authorization templates</u> for molecular diagnostic tests for developers that intend their assay to be used for pooling patient samples or for screening asymptomatic individuals not suspected of having COVID-19.
- June 10: The FDA <u>issued</u> an Emergency Use Authorization (EUA) for the first COVID-19 diagnostic test using next-generation sequencing technology. The Illumina COVIDSeq Test detects COVID-19 by using technology that can determine the genetic sequence of the virus through collected respiratory specimens.
- **June 4:** The FDA has <u>published</u> antibody test performance data from four serology tests kits from its independent performance validation study effort with the National Institutes of Health's (NIH) National Cancer Institute (NCI).
- **June 3:** The FDA <u>announced</u> a resource titled Testing Supply Substitution Strategies, that provides detailed information on validated supply alternatives that labs can use to continue performing COVID-19 diagnostic tests when there is a supply issue with components of the test.
- 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>).

- May 16: The FDA <u>issued</u> the first Emergency Use Authorization (EUA) for a standalone athome sample collection kit that can then be sent to specified laboratories for COVID-19 diagnostic testing.
- **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 <u>summary</u>).
- **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 <u>COVID-19 Diagnostic FAQ</u> 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 summary).

Medical Devices

- **February 9:** The FDA <u>issued</u> a letter to health care providers on using ventilator splitters in situation in which no alternatives for invasive ventilatory support are available.
- **August 11:** The FDA issued new frequently asked questions (FAQs) document on <u>importing</u> medical devices during the pandemic, and <u>registration and listing of medical devices during the pandemic</u>.
- **June 25:** The FDA <u>updated</u> its list of Emergency Use Authorizations (EUAs) for ventilators and ventilator accessories. The list now includes 68 ventilators and 17 ventilator accessories.

- **June 22:** The FDA <u>issued</u> guidance to answer frequently asked questions (FAQs) on the impact of the COVID-19 public health emergency (PHE) on formal meetings and user fee applications for medical devices.
- **June 19:** The FDA <u>updated</u> its guidance on notifying the Center for Devices and Radiological Health (CDRH) of a permanent discontinuance or interruption in manufacturing of a device under Section 506J of the Food, Drug, and Cosmetic Act during the COVID-19 public health emergency.
- **June 1:** The FDA <u>announced</u> the process for publishing Emergency Use Authorizations (EUAs) for medical devices related to the COVID-19 public health emergency (WHG client <u>summary</u>)
- **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 public health emergency (PHE) (WHG client summary).
- **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 summary).
- 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 here.

Funding Opportunities and Awards

- *NEW* March 26: The complete breakdown of all COVID-19 funding made available by Congress and provided through various awards is available here.
- **December 8:** CDC announced a grant opportunity (<u>CDC-RFA-1P21-2016</u>) aimed at increasing COVID-19 and flu vaccination coverage in racial and ethnic populations experiencing disparities in vaccination rates (WHG client summary).
- November 17: CDC announced a pediatric immunization-focused Notice of Funding
 Opportunity (NOFO) US Enhanced Surveillance Network to Assess Burden, Natural History,
 and Effectiveness of Vaccines to Prevent Enteric and Respiratory Viruses in Children (<u>RFA-IP-21-002</u>) (WHG client <u>summary</u>).
- **September 29:** CDC released a report that found that the incidence of COVID-19 cases in children aged 12-17 years nearly doubled the incidence of COVID-19 cases in children aged 5-11 years. (WHG client <u>summary</u>).
- **September 23:** CDC <u>announced</u> \$200 million in supplemental funding to 64 jurisdictions to support COVID-19 vaccine preparedness (WHG client summary).
- **September 1:** CDC issued an <u>agency order</u> effectuating a four-month temporary halt in residential evictions in the U.S., through on December 31, 2020. (WHG client <u>summary</u>).
- **July 28:** CDC announced a supplemental funding opportunity (<u>CDC-RFA-OT18-18020302SUPP20</u>) titled, "Strengthening Public Health Systems and Services through National Partnerships to Improve and Protect the Nation's Health." The application deadline is August 10, 2020 (WHG client <u>summary</u>).

- **June 3:** CDC announced a funding opportunity (<u>CDC-RFA-TS19-19010201SUPP20</u>) to provide Pediatric Environmental Health Specialty Units (PEHSUs) with supplemental funding to support their COVID-19 response efforts (WHG client summary).
- 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 award \$186 million in supplemental funding to states and local jurisdictions to support their public health infrastructure. Specifically, \$160 million will be provided through the Public Health Crisis Response Cooperative Agreement (CoAg) and \$26.3 million will be provided through the Emerging Infections Program (EIP). In addition, \$80 million in supplemental funding is underway for tribal governments and organizations. The funding was made available through the Phase I COVID-19 package. See here for supplemental funding data by jurisdiction.
- April 2: CDC issued a funding opportunity titled, "COVID-19 Response Supplement Part B: Tribal Public Health Capacity-Building and Quality Improvement Umbrella Cooperative Agreement" (CDC-RFA-OT18-18030203SUPP20). The application deadline is April 8, 2020.
- April 1: CDC issued a funding opportunity titled, "Supporting Tribal Public Health Capacity in Coronavirus Preparedness and Response" (<u>CDC-RFA-OT20-2004</u>). Approximately \$40 million was made available under the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (<u>H.R. 6074</u>) (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 <u>summary</u>).

For Providers and Public Health Professionals

- **September 11:** NIOSH, part of the CDC, announced a request for information regarding the use of "elastomeric half-mask respirators" in healthcare settings during the COVID-19 pandemic to "ease the demand for single-use N95 filtering facepiece respirators (FFRs). (WHG client summary).
- 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 summary).
- **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 <u>Morbidity and Mortality Weekly Report (MMWR)</u> 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</u> for healthcare professionals on COVID-19 regarding whether pregnant health care personnel are at increased risk if they care for patients with COVID-19.
 CDC recommends pregnant healthcare personnel to follow risk assessment and infection control guidelines for personnel exposed to patients with suspected or confirmed COVID-19.
- March 11: HHS <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

- October 5: CDC updated its <u>"How COVID is Spread"</u> webpage to acknowledge the potential airborne transmission of COVID-19.
- **August 24:** CDC revised COVID-19 testing guidance to state that individuals who have been in close contact with a person known to have COVID-19 and do not exhibit symptoms (i.e., are asymptomatic) may not need to be tested (WHG client summary).
- **July 14**: CDC Director Dr. Robert Redfield, along with other lead scientists, published an editorial calling on Americans to wear cloth face masks to slow the spread of COVID-19, citing increasing evidence that cloth faces help prevent people who have COVID-19 from spreading the virus to others (press release).
- **June 30**: The CDC <u>issued</u> interim considerations for institutions of higher education administrators for COVID-19 testing as college and universities reopen.
- **June 17**: CDC submitted its <u>updated report</u> on COVID-19 demographic data to Congress, as required by the Paycheck Protection Program and Health Care Enhancement Act (WHG client <u>summary</u>).
- May 28: CDC released guidance for employers on how to create a safe and healthy workplace in an office building and protect workers and clients from COVID-19.
- May 20: CDC <u>released</u> resources to assist states to reopen, which includes <u>CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again.</u>
- May 14: CDC released reopening guidance for <u>workplaces</u>, <u>mass transit</u>, <u>schools</u>, <u>child care programs</u>, <u>restaurants and bars</u>, and <u>youth programs and camps</u>.

- **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* March 29: HHS <u>announced</u> \$100 million in grants to the Aging and Disability Networks in every state and territory to expand access to COVID-19 vaccines for older adults and people with disabilities.
- *NEW* March 17: The Biden Administration <u>announced</u> that HHS is investing \$150 million to increase access to COVID-19 monoclonal antibody therapeutic treatments for patients in underserved communities (WHG client <u>summary</u>).
- *NEW* March 12: HHS <u>issued</u> an amendment to the Public Readiness and Emergency Preparedness (PREP) Act to add additional categories of qualified people authorized to prescribe, dispense, and administer COVID-19 vaccines, including dentists, EMTs, midwives, optometrists, paramedics, physician assistants, podiatrists, respiratory therapists, and veterinarians.
- *NEW* March 12: HHS <u>issued</u> a fact sheet detailing how the American Rescue Plan reduces health care costs, expands access to insurance coverage, and addresses health care disparities.
- *NEW* March 11: HHS <u>announced</u> that an additional 700 Health Resources and Services Administration (HRSA)-supported health centers will be invited to join the Health Center COVID-19 Vaccine Program.
- *NEW* March 8: HHS <u>announced</u> \$250 million for the <u>Advancing Health Literacy to Enhance Equitable Community Responses to COVID-19</u> initiative to encourage COVID-19 safety and vaccination among underserved populations.
- *NEW* March 2: HHS <u>announced</u> a manufacturing collaboration between Merck and Johnson & Johnson to expand the production of the J&J one dose COVID-19 vaccine.
- **February 23:** HHS issued a <u>Notification of Enforcement Discretion</u> stating that the HHS OCR will not impose penalties for noncompliance with regulatory requirements under the HIPAA rules for scheduling individual appointments for COVID-19 vaccination (WHG client summary).

- **February 11:** HHS and the Department of Defense (DOD) <u>announced</u> the purchase of 100 million additional COVID-19 vaccine doses from Pfizer and Moderna.
- **February 11:** HHS announced a <u>sixth amendment</u> to its declaration under the Public Readiness and Emergency Preparedness (PREP) Act to clarify that federal personnel are protected as qualified persons. (WHG client <u>summary</u>).
- **January 29:** HHS <u>announced</u> it is extending its designation preventing the hoarding of certain materials needed for the ongoing COVID-19 response through June 20, 2021.
- **January 28:** HHS <u>issued</u> an amendment to its March 2020 <u>Declaration</u> under the Public Readiness and Emergency Preparedness (PREP) Act to expand the workforce of health care providers who can administer COVID-19 vaccines (WHG client summary).
- **January 28:** HHS <u>announced</u> the opening of a Special Enrollment Period (SEP) for individuals and families for marketplace coverage in response to the COVID-19 pandemic.
- **January 19:** HHS <u>announced</u> it will exercise enforcement discretion and not impose penalties for violations of HIPAA Rules for providers in good faith using web-based platforms to schedule individual vaccination appointments for COVID-19.
- **January 19:** HHS <u>awarded</u> \$20 million in funds from the Coronavirus Aid, Relief, and Economic Security (CARES) Act to help increase data sharing between health information exchanges and immunization information systems.
- **January 15:** HHS <u>announced</u> reporting updates for the Provider Relief Fund (WHG client summary).
- **January 13:** HHS updated its <u>guidance</u> to hospitals for reporting COVID-19 data. Specifically, HHS is now requesting that hospitals report vaccine administration data once per week.
- **January 11**: HHS <u>announced</u> the launch of a web-based COVID-19 outpatients <u>treatment locator</u> to assist healthcare providers and patients in finding potential locations for treatment with monoclonal antibody therapeutics.
- **January 6:** HHS <u>announced</u> a series of actions out of the Centers for Disease Control and Prevention (CDC) to distribute over \$22 billion in funding to support COVID-19 testing and vaccination distribution.
- **December 23:** HHS <u>announced</u> the purchase of 100 million additional Pfizer COVID-19 doses.
- **December 18:** HHS and the Department of Defense (DOD) <u>announced</u> a \$356 million contract with Merck to support advanced development and large-scale manufacturing of their investigational COVID-19 treatment.
- **December 16:** HHS <u>announced</u> it has completed review of Phase 3 applications for the Provider Relief Fund (PRF) and will distribute approximately \$24.5 billion to over 70,000 providers (WHG client <u>summary</u>).

- December 16: HHS <u>announced</u> sixteen winning designs from <u>the HHS COVID-19 At-Anywhere</u> <u>Diagnostics Design-a-thon</u> aimed to increase speed, quality, comprehensiveness, and utility of COVID-19 diagnostic test data.
- **December 15:** HHS <u>announced</u> that the Centers for Disease Control and Prevention (CDC) will award \$140 million for COVID-19 vaccine preparedness and \$87 million for tracking and tracing to 64 jurisdictions.
- **December 11:** HHS and DoD <u>announced</u> the purchase of an additional 100 million doses of Moderna's COVID-19 vaccine candidate.
- **December 7:** HHS <u>announced</u> the release of hospital COVID-19 capacity data at the facility level. Previously, data was only available at the state level.
- **December 7:** HHS <u>announced</u> the release of \$523 million in performance-based incentive payments to eligible nursing homes starting December 9 (WHG client <u>summary</u>).
- December 3: HHS <u>issued</u> an amendment to the Public Readiness and Emergency Preparedness (PREP) Act to increase access to countermeasures, including COVID-19 tests via telehealth (WHG client <u>summary</u>).
- **December 3:** HHS <u>announced</u> that all tribal health programs and Urban Indian Organizations (UIOs) have chosen their preferred method of receiving COVID-19 vaccines.
- **November 24:** HHS issued a <u>request for information</u> about effective and innovative approaches/best practices in health care in response to the COVID-19 pandemic. Comments are due Dec. 24 (WHG client <u>summary</u>).
- **November 23:** HHS and DoD <u>announced</u> a \$11.6 million contract with Puritan Medical Products to increase U.S. production of swabs for Cue Health COVID-19 tests.
- **November 23:** HHS <u>announced</u> plans to allocate initial doses of Regeneron's investigational monoclonal antibody therapeutic for treatment of non-hospitalized patients with mild or moderate confirmed cases of COVID-19 at high risk of hospitalization.
- **November 19:** HHS and DoD <u>announced</u> a \$12 million contract with Siemens Healthineers to support domestic production of two coronavirus diagnostic tests.
- **November 19:** HHS <u>launched</u> a pilot program to use rapid, point-of-care COVID-19 molecular test kits in Alaska, Florida, Louisiana, New Jersey, and Texas.
- **November 18:** HHS <u>updated</u> its FAQs for the Provider Relief Fund and clarified two key points related to reporting requirements (WHG client <u>summary</u>).
- **November 12:** HHS <u>announced</u> partnerships with independent pharmacies and regional chains throughout the nation to participate in the federal allocation of future COVID-19 vaccines.

- **November 10:** HHS <u>announced</u> plans to allocate 300,000 doses of Eli Lilly's monoclonal antibody therapy, bamlanivimab, to state and territorial health departments, who will then distribute the doses to health care facilities.
- October 31: HHS <u>announced</u> that 389,040 Abbott BinaxNOW COVID-19 rapid tests have been distributed at no cost to 83 Historically Black Colleges and Universities in 24 states.
- October 31: HHS and DoD <u>announced</u> an \$12.7 million contract with InBios International to increase production of rapid COVID-19 tests to 20 times current capacity by May 2021.
- October 30: HHS and DoD <u>announced</u> an \$119 million agreement with Hologic to expand production capacity for COVID-19 tests to 13 million per month by January 2022.
- October 30: HHS <u>briefed</u> governors on COVID-19 response and vaccine distribution best practices. The agency also released its response to governors' technical questions.
- October 30: HHS <u>announced</u> that COVID-19 ancillary supply kits will be distributed alongside vaccine orders at no cost to enrolled COVID-19 vaccination providers.
- October 28: HHS <u>announced</u> it is distributing \$333 million in incentive payments, for keeping COVID-19 infection and mortality rates low, to 77 percent of participating nursing homes.
- October 28: HHS and DoD <u>announced</u> an agreement with Eli Lilly to purchase 300,000 doses of the company's COVID-19 antibody drug for \$375 million.
- October 25: HHS <u>announced</u> states have begun reporting information about their <u>plans</u> to use rapid point-of care COVID-19 tests which the administration began distributing in September.
- October 22: HHS <u>revised</u> Provider Relief Fund (PRF) eligibility and reporting requirements for its forthcoming "Phase 3" general distribution (WHG client <u>summary</u>).
- October 21: HHS <u>issued</u> guidance authorizing qualified pharmacy technicians and stateauthorized pharmacy interns to administer childhood vaccines, COVID-19 vaccines, and COVID-19 tests (WHG client <u>summary</u>).
- October 16: Effective October 16, HHS <u>announced</u> that communities that are part of the federal surge testing effort for COVID-19 can now use a saliva test to detect SARS-CoV-2.
- October 16: HHS and DoD <u>announced</u> agreements with CVS and Walgreens to provide and administer COVID-19 vaccines to residents of long-term care facilities with no out-of-pocket costs (WHG client <u>summary</u>).
- October 13: HHS and DoD <u>announced</u> a \$31 million agreement with Cytiva to expand manufacturing capacity for the "vaccine-related consumable products" necessary to produce COVID-19 vaccines.
- October 13: HHS, in collaboration with DoD, <u>awarded</u> \$481 million to Cue Health, Inc. to expand U.S. production capacity for a cartridge-based point-of-care COVID-19 molecular test.

As part of the deal, Cue Health will deliver six million COVID-19 tests and 30,000 instruments to the U.S. government.

- October 9: HHS <u>announced</u> an expanded partnership with AstraZeneca for late-stage development and large-scale manufacturing of the company's COVID-19 monoclonal antibody cocktail. BARDA and DoD will contribute roughly \$486 million for two Phase 3 clinical trials and other development activities.
- October 1: HHS <u>announced</u> a Phase 3 General Distribution of \$20 billion from the Provider Relief Fund. The funds will be open to previously ineligible providers and will also permit those who have already received funds to apply for additional funding that considers financial losses and changes in operating expenses due to the pandemic (WHG client <u>summary</u>).
- October 1: HHS <u>announced</u> a pilot program with The Rockefeller Foundation to identify and share effective approaches for using rapid point-of-care antigen tests to screen for COVID-19 in communities, particularly to safely reopen K-12 schools.
- October 1: HHS <u>announced</u> American hospitals can now purchase remdesivir directly from the manufacturer.
- **September 30:** HHS <u>announced</u> five cooperative agreements, funded by the CARES Act, with health information exchange organizations (HIEs) to improve interoperability of health data.
- **September 28:** HHS <u>announced</u> the distribution plan for the 150 million Abbott BinaxNOW Ag Card rapid point-of-care COVID-19 tests to states.
- **September 23:** HHS <u>announced</u> the CDC will provide \$200 million to 64 jurisdictions (see details <u>here</u>) for COVID-19 vaccine preparedness as part of an existing Immunizations and Vaccines for Children cooperative agreement.
- **September 19:** HHS <u>released</u> long-awaited reporting requirements for funds obtained via the Provider Relief Fund (PRF). The newly released requirements contain significant changes from the guidance HHS previously released in July. (WHG client <u>summary</u>).
- **September 9:** The Office of the Assistant Secretary for Health (OASH) issued <u>guidance</u> under the Public Readiness and Emergency Preparedness Act (PREP Act) that expands authorization for certain pharmacists to order and administer COVID-19 vaccinations (WHG client <u>summary</u>).
- **September 9:** The Office of the Assistant Secretary for Health (OASH) <u>released</u> an RFI seeking information to assess whether CLIA-certified/accredited laboratories are able to provide additional COVID-19 testing if testing equipment from Thermo Fisher Scientific were made available (WHG client <u>summary</u>).
- **September 3:** HHS <u>released</u> details about the \$2 billion Provider Relief Fund (PRF) performance-based incentive payment distribution to nursing homes (WHG client <u>summary</u>).
- **September 2:** HHS <u>announced</u> that assisted living facilities may now apply for funding under the Provider Relief Fund Phase 2 General Distribution allocation (WHG client summary).

- August 28: HHS and the Department of Defense (DOD) <u>announced</u> a \$760 million contract with Abbott for 150 million Abbott BinaxNOW COVID-19 Ag Card point-of-care diagnostic tests (WHG client summary).
- **August 27:** HHS, through the Health Resources and Services Administration (HRSA) <u>announced</u> the distribution of \$2.5 billion to nursing homes to support increased testing, staffing, and personal protective equipment (PPE) needs (WHG client <u>summary</u>).
- August 25: HHS extended the deadline to apply for Phase 2 General Distribution Funding from the Provider Relief Fund (PRF) to September 13 and noted that reporting requirements for recipients of provider relief funds that were slated to be released on August 17 will be released at a later date. (WHG client summary).
- August 25: HHS <u>announced</u> the release of 1.5 million N95 respirators from the Strategic National Stockpile (SNS) for distribution to 3,336 nursing home facilities (WHG client <u>summary</u>).
- **August 20:** HHS <u>announced</u> that the Defense Production Act is being leveraged for contracts with Becton Dickinson and Quidel Corporation for large volume purchase of diagnostic systems and assays for COVID-19 testing (WHG client <u>summary</u>).
- August 19: HHS <u>issued</u> an <u>amendment</u> to increase access to childhood vaccines under the Public Readiness and Emergency Preparedness (PREP) Act for Medical Countermeasures Against COVID–19.
- **August 14:** HHS <u>announced</u> McKesson will distribute future COVID-19 vaccines and supplies as part of an option the federal government is exercising under a 2016 contract.
- **August 14:** HHS <u>announced</u> a \$1.4 billion Provider Relief Fund disbursement to free-standing children's hospitals (WHG client summary).
- **August 12:** HHS <u>announced</u> a \$6.5 million investment to ramp up national COVID-19 testing capacity (WHG client <u>summary</u>).
- **August 12:** HHS <u>announced</u> a funding opportunity, authorized by the CARES Act, to increase and fast-track the use of health information exchanges (HIEs) and improve linkages between state and local public health agencies (WHG client <u>summary</u>).
- **August 11:** HHS and the DoD <u>announced</u> a \$1.5 billion deal with Moderna to support vaccine manufacturing and delivery of 100 million doses. The contract includes an option to acquire another 400 million doses (WHG client <u>summary</u>).
- August 10: HHS <u>announced</u> that that certain eligible Medicare providers may now submit <u>applications</u> to receive additional Provider Relief Fund payments. Applications will be accepted through August 28, as described in an <u>announcement</u> on July 31 (WHG client summary).
- August 10: HHS <u>announced</u> it has <u>posted</u> updated COVID-19 state testing plans for July through December (WHG client <u>summary</u>).

- **August 7:** HHS <u>released</u> additional information about the \$5 billion Provider Relief Fund allocation to nursing homes <u>announced</u> by CMS in July.
- August 7: HHS released a <u>fact sheet</u> explaining Operation Warp Speed and highlighting the
 actions taken to advance COVID-19 countermeasure development, manufacturing, and
 distribution to date (WHG client <u>summary</u>).
- August 5: HHS and the DoD <u>announced</u> a \$1 billion deal with Johnson & Johnson to support vaccine development and purchase 100 million doses. The contract includes an option to purchase another 200 million doses (WHG client <u>summary</u>).
- **July 31:** HHS <u>announced</u> it is extending the Provider Relief Fund application period for Medicaid and CHIP providers through August 28. It will also permit Medicare providers who missed the chance to apply for the second \$20 billion tranche of general provider relief, and providers with ownership changes in 2020, to apply for funding the week of August 10 through August 28 (WHG client summary).
- **July 31:** HHS <u>highlighted</u> recent testing statistics and described the actions being taken to decrease COVID-19 testing turnaround times.
- **July 31:** HHS and the DoD <u>awarded</u> Sanofi and GlaxoSmithKline \$2.1 billion to support vaccine development and purchase 100 million doses. The contract includes an option to purchase another 500 million doses (WHG client <u>summary</u>).
- **July 30:** HHS <u>announced</u> an \$8 million advertising campaign, featuring PSAs from top health officials, to urge Americans who have recovered from the coronavirus to donate plasma. The campaign seeks to substantially increase convalescent plasma donations by the end of August.
- **July 29:** HHS, through the Assistant Secretary for Planning and Evaluation (ASPE), released a report on surprise medical billing (press release) (WHG client summary).
- **July 28:** HHS, through the Assistant Secretary for Planning and Evaluation (ASPE), released a report on Medicare beneficiary telehealth utilization during the COVID-19 pandemic (press release)(WHG client summary).
- **July 28:** HHS, the Department of Veterans Affairs, and the Department of Energy <u>announced</u> the COVID-19 Insights Partnership, an initiative that uses high-performance computing and artificial intelligence to coordinate and share health data, research, and expertise.
- **July 27:** HHS <u>announced</u> a \$265 million task order that reserved the available advanced manufacturing capability and capacities of the Center for Innovation in Advanced Development and Manufacturing at the Texas A&M University system for COVID-19 vaccine manufacturing.
- **July 26:** HHS and the DoD <u>awarded</u> Hologic Inc. a \$7.6 million contract to expand production of custom sample collection and processing consumables for COVID-19 testing (WHG client summary).
- **July 22:** HHS and the DoD <u>announced</u> an agreement with Pfizer for large-scale production and delivery of 100 million doses of a COVID-19 vaccine after the vaccine's successful manufacture

- and approval. The agreement also permits the federal government to obtain an additional 500 million doses (WHG client summary).
- **July 21:** HHS <u>announced</u> the *National Testing Implementation Forum* to share information and provide input to federal leaders about SARS-CoV-2 testing and diagnostics.
- **July 20:** HHS <u>released</u> FAQs about HHS Protect, the new data and analytics platform that replaced the CDC's NHSN system to track COVID-19 data.
- **July 20:** HHS restored <u>public access</u> to COVID-19 data that hospitals report to the government.
- **July 17:** HHS <u>announced</u> it will distribute another \$10 billion to providers in COVID-19 hotspots (WHG client <u>summary</u>).
- **July 15:** HHS <u>released</u> prepared remarks from a media call with CDC Director Redfield and CIO Arrieta on recent COVID-19 data collection changes.
- **July 14:** HHS <u>announced</u> it will ramp up testing at nursing homes in COVID-19 hotspots using rapid point-of-care diagnostic test instruments.
- **July 10:** HHS sent a <u>letter</u> to hospitals telling them to stop reporting COVID-19 data through the CDC's National Healthcare Safety Network (NHSN) (WHG client <u>summary</u>).
- **July 10:** HHS <u>announced</u> an additional \$4 billion in Provider Relief Fund disbursements. \$3 billion will be distributed to <u>safety net hospitals</u> that have less than 3% profitability averaged over 2 or more of its last 5 cost report filings, and \$1 billion will go to small city and <u>rural health</u> <u>providers</u>. Additionally, dentists can now apply for reimbursements of 2% of their annual reported patient revenue through an <u>application portal</u> created in June.
- **July 10:** HHS released the May and June COVID-19 testing plans from all states, territories, and localities. Testing plan by state and jurisdiction can be found here (WHG client summary).
- **July 9:** HHS <u>announced</u> the distribution of \$21 million through the Health Resources and Services Administration (HRSA) to support health centers' COVID-19 response efforts. More than \$17 million was awarded to 78 Health Center Program look-alikes to expand COVID-19 testing.
- **July 8:** HHS <u>announced</u> the launch of 'surge' COVID-19 testing in Jacksonville, Florida; Baton Rouge, Louisiana; and Edinburg, Texas, to address the recent increase in cases.
- **July 7:** HHS <u>announced</u> a \$450 million agreement with Regeneron through <u>Operation Warp Speed</u> to demonstrate commercial-scale manufacturing of an investigational COVID-19 treatment. The federal government will own the approximately 70,000 300,000 doses produced via the demonstration.
- **July 7:** HHS <u>announced</u> a \$1.6 billion agreement with Novavax through <u>Operation Warp Speed</u> to demonstrate commercial-scale manufacturing of an investigational COVID-19 vaccine. The federal government will own the 100 million doses produced via the demonstration.

- **July 1:** HHS <u>announced</u> it is extending its partnership with national pharmacy and grocery retail chains to continue to provide access to COVID-19 testing as part of the <u>Community-Based Testing Program</u>.
- June 30: HHS <u>announced</u> the Trump Administration is re-establishing the Ready Reserve Corps as part of the United States Public Health Service (USPHS). Authorization was included in the CARES Act. The USPHS Commissioned Corps will accept Ready Reserve Corps applications online beginning in Fall 2020.
- **June 29:** HHS announced that it has secured over 500,000 doses of Gilead's remdesivir for the treatment of COVID-19. Shipments of the product will occur every two weeks and hospitals will pay no more than the Wholesale Acquisition Cost of \$3,200 per treatment course.
- **June 23:** HHS <u>awarded</u> Morehouse School of Medicine \$40 million to lead an initiative with the Office of Minority Health that will coordinate delivery of COVID-19-related information to communities hardest hit by the pandemic.
- **June 22:** HHS <u>announced</u> it has awarded \$107.2 million to 310 recipients to increase the health workforce in rural and underserved communities.
- **June 16:** HHS released a <u>fact sheet</u> about Operation Warp Speed which details the plan for development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics by January 2021.
- **June 11:** HHS <u>awarded</u> \$8 million to expand COVID-19 training and technical assistance for health centers. \$6 million was granted to <u>primary care associations</u> and \$2.5 million went to <u>national training and technical assistance partners</u>.
- **June 9:** HHS <u>announced</u> \$15 billion in Provider Relief Fund payments for Medicaid and CHIP providers and \$10 billion for safety net hospitals. The agency also indicated a second round of hot spot funding totaling \$10 billion is imminent.
- **June 4:** HHS <u>released</u> new <u>guidance</u>, as directed by the CARES Act, specifying the additional data laboratories must report to HHS with COVID-19 test results. More information is available in the <u>FAQs</u> (WHG client <u>summary</u>).
- **June 1:** Through BARDA, and as part of the Administration's Operation Warp Speed, HHS <u>awarded</u> a \$628 million contract to Emergent BioSolutions to increase the country's vaccine manufacturing capacity.
- May 28: HHS <u>awarded</u> \$15 million to 52 Tribes, Tribal organizations, urban Indian health organizations, and other tribal health services providers across 20 states, to respond to COVID-19 in rural tribal communities. The list of Rural Tribal COVID-19 Response program award recipients is available <u>here</u>.
- May 24: HHS <u>submitted</u> its COVID-19 Strategic Testing Plan report to Congress as required by the Paycheck Protection Program and Health Care Enhancement Act.

- May 22: HHS <u>announced</u> a 45-day deadline extension for providers to accept the Terms and Conditions for receiving payments from the Provider Relief Fund (WHG client <u>summary</u>).
- 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.
- 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>).
- May 21: HHS <u>announced</u> 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.
- 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.
- 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>.
- **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.
- 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 here.
- May 15: The Trump Administration <u>announced</u> 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.
- 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 <u>summary</u>)
- 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 here.

- **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 <u>here</u>.
- **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 summary).
- **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 <u>here</u>.

- **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 here.
- **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 here.
- 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>) <u>guidance</u> 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 summary).
- **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 here.
- 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

- **August 24:** OCR issued <u>amended guidance</u> on how the HIPPA Rule allows health care providers and health plans to contact recovered COVID-19 patients about how to donate convalescent plasma for treatment purposes (press release) (WHG client summary).
- **July 21:** OCR announced two resolutions to protect religious rights within health care settings during the COVID-19 pandemic. The <u>first</u> is related to religious visitation, and the <u>second</u> involves religious accommodation related to the use of PPE.
- **July 20:** OCR issued (<u>press release</u>) <u>guidance</u> for recipients of federal financial assistance on civil rights protections prohibiting discrimination on the basis of race, color, and national origin during the COVID-19 pandemic.
- **June 12:** OCR issued (<u>press release</u>) <u>guidance</u> about how health care providers can contact their patients who have recovered from COVID-19 to inform them about opportunities to donate blood and plasma.
- 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> of <u>Enforcement Discretion</u> during the COVID-19 nationwide public health emergency.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

- **December 3:** ASPR <u>announced</u> it is collaborating with Chembio Diagnostics on the development of two rapid point-of-care diagnostic tests to both detect antigens for COVID-19 and detect and differentiate Influenza from COVID-19.
- **December 2:** ASPR <u>announced</u> the purchase of 650,000 additional treatment courses of Eli Lilly's investigational monoclonal antibody therapeutic, bamlanivimab, to be delivered in December and January for treatment of non-hospitalized COVID-19 patients.
- **November 24:** BARDA <u>announced</u> a partnership with Siemens Healthineers to accelerate development of the SARS-CoV-2 Antigen assay (CoV2Ag).
- **November 16:** BARDA <u>announced</u> it has expanded its partnership with DiaSorin Inc. to develop an enhanced immunoassay for determining COVID-19 patient exposure and immune status.
- **November 6:** BARDA and DoD <u>announced</u> they will provide technical assistance to Humanigen, Inc. on a Phase 3 clinical trial of a drug that is being developed to prevent or treat an immune hyper-response caused by COVID-19.
- **November 6:** BARDA <u>announced</u> it will support Mesa Biotech, Inc. in the development of a rapid combination test for influenza A/B and COVID-19.
- October 19: BARDA <u>announced</u> a partnership with Technical Resources International, Inc. (TRI) to support an adaptive phase 3 clinical trial that will evaluate three immune modulator drugs in treating hospitalized adults with COVID-19.
- October 15: BARDA <u>announced</u> it will fund a clinical trial to validate Beckman Coulter's method for rapid detection of Multisystem Inflammatory Syndrome in Children (MIS-C), a severe complication of SARS-CoV-2 infection in children.

- October 7: BARDA <u>announced</u> a partnership with Current Health to develop a digital biomarker-based algorithm that can predict the need for hospitalization and ICU level care for patients with COVID-19.
- October 7: BARDA and DoD <u>announced</u> a partnership with Cepheid to develop a single, rapid diagnostic test to detect COVID-19, influenza, and respiratory syncytial virus (RSV).
- October 6: BARDA <u>announced</u> a \$22 million, 3-year agreement with Vaxxas to develop a patch that can administer vaccines without traditional needles.
- **September 24:** BARDA <u>announced</u> it is continuing its partnership with Luminex Corporation on the development of a rapid, high-throughput COVID-19 test on the NxTAG® Respiratory Pathogen Panel, which will be submitted for both EUA and 510(k) approval.
- **September 23:** BARDA <u>announced</u> a partnership with Luminex Corporation to develop a cost effective, high throughput test that assesses the ability of antibodies in plasma to bind with and prevent SARS-CoV-2 from interacting with human cells.
- **September 17:** BARDA and DoD <u>announced</u> a partnership with Ology Bioservices that will expand domestic fill-finish capacity for COVID-19 vaccines and therapeutics under Operation Warp Speed.
- August 31: BARDA <u>announced</u> is it collaborating with NOWDiagnostics, Inc. to develop a rapid, point-of-care and over-the-counter, in vitro diagnostic test to detect SARS-CoV-2 antibodies.
- August 6: BARDA and DoD <u>announced</u> a partnership with Grand River Aseptic Manufacturing that will expand domestic fill-finish capacity for COVID-19 vaccines and therapeutics under Operation Warp Speed.
- **August 6:** BARDA <u>announced</u> it is expanding its relationship with DiaSorin, Inc. by supporting a second COVID-19 antibody test.
- **July 28:** BARDA <u>announced</u> it is expanding its relationship with Moderna to support the Phase 3 clinical trial of Moderna's COVID-19 vaccine candidate.
- **June 2:** HHS <u>announced</u> that ASPR is providing an additional \$250 million to support health care systems responding to the COVID-19 pandemic through funding appropriated by the CARES Act. More information is available <u>here</u>.
- **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 <u>announced</u> 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 <u>summary</u>).
- 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 <u>summary</u>).
- March 13: The Biomedical Advanced Research and Development Authority (BARDA) within ASPR provided advanced support to rapidly develop two diagnostic tests for COVID-19, Simplexa COVID-19 Direct Assay and QIAstat-Dx RPS2 test.
- March 9: ASPR <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* March 29: OIG reported new COVID-19 enforcement actions.
- *NEW* March 25: OIG updated its COVID-19 fraud alert information.
- *NEW* March 24: OIG released a <u>report</u> detailing how the COVID-19 pandemic has affected the ability of hospitals to deliver care. It provides an updated snapshot of hospital administrators' views in February 2021, nearly a year after the first "pulse survey" in March 2020.
- *NEW* March 24: OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- *NEW* March 15: OIG <u>revamped</u> its COVID-19 portal and <u>posted</u> new COVID-19 work plan items.
- *NEW* March 8: OIG updated its COVID-19 fraud alert information.
- **February 26:** OIG <u>released</u> a statement about the use telehealth during the COVID-19 public health emergency.

- **February 17:** OIG <u>updated</u> FAQs about its administrative enforcement authorities related to COVID-19 public health emergency arrangements.
- **February 4:** OIG released a <u>report</u> describing opioid use in Medicare Part D during the first eight months of the COVID-19 pandemic.
- **January 29:** OIG posted new COVID-19 work plan items.
- **January 15:** OIG posted new COVID-19 work plan items.
- **January 14:** Multi-OIG <u>report</u> examines COVID-19 testing for six federal health care programs between February 1, 2020 and August 31, 2020.
- **December 17:** OIG <u>released</u> a review of states' onsite surveys of nursing homes during the COVID-19 pandemic, between March 23 and May 30, 2020.
- **December 15:** OIG posted a new COVID-19 work plan item.
- **December 14:** OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- **December 10:** OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- **December 3:** OIG updated its COVID-19 fraud alert information.
- **November 23:** OIG <u>issued</u> a report about the challenges opioid treatment programs have encountered during the COVID-19 pandemic and the actions taken to address them.
- November 23: OIG updated its COVID-19 fraud alert information.
- **November 3:** OIG <u>updated</u> its COVID-19 fraud alert information.
- October 26: OIG posted new COVID-19 work plan items.
- October 21: OIG updated its COVID-19 fraud alert information.
- October 2: OIG posted new COVID-19 work plan items.
- October 1: OIG posted an <u>audit</u> of the Child Care and Development Fund (CCDF) program. The audit was conducted to provide a national picture of how states dealt with the issues posed by the COVID-19 pandemic in child care settings.
- **September 21:** OIG posted new COVID-19 work plan items.
- **September 3:** OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.

- August 28: OIG posted a new COVID-19 work plan item.
- **August 4:** OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- **August 3:** OIG <u>released</u> emergency response tool kits that include key insights from OIG reports on preparedness and response (WHG client <u>summary</u>).
- **July 30:** OIG <u>updated</u> FAQs about its administrative enforcement of arrangements connected to the COVID-19 public health emergency.
- May 26: OIG <u>released</u> its strategic plan for oversight of COVID-19 response and recovery (WHG client <u>summary</u>).
- 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

- *NEW* February 26: The Department of Labor, Treasury, and the Department of Health and Human Services (HHS) released <u>guidance</u> that requires plans to cover COVID diagnostic testing of asymptomatic patients without known exposure (WHG client <u>summary</u>).
- *NEW* February 26: The Employee Benefits Security Administration (EBSA) issued <u>Guidance</u> on Continuation of Relief for Employee Benefit Plans and Plan Participants and Beneficiaries <u>Due to the COVID-19 (Novel Coronavirus) Outbreak (WHG client summary).</u>
- June 23: The Department of Labor's Employee Benefits Security Administration (EBSA) issued FAQs about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act implementation. The FAQs discuss requirements on health plans and health insurance issuers offering group or individual health insurance coverage regarding coverage, reimbursement, and notice requirements, as well as telehealth services, grandfathered health plans, mental health parity, wellness programs, and HRAs.
- 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 <u>here</u>.
- May 4: The Department of Labor's Employee Benefits Security Administration (EBSA) and the Department of Treasury's Internal Revenue Service (IRS) issued a <u>final rule</u> extending certain time frames for group health plans, disability and other employee welfare benefit plans, employee pension benefit plans, and their participants and beneficiaries under ERISA and the Internal Revenue Code (WHG client <u>summary</u>).
- 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 <u>summary</u>).
- **April 4:** Employment and Training Administration releases guidance to states on the Federal Pandemic Unemployment Compensation program (WHG client summary).

NATIONAL INSTITUTES OF HEALTH

- *NEW* March 24: The NIH announced new findings that SARS-CoV-2 infects mouth cells.
- *NEW* March 23: The Data and Safety Monitoring Board (DSMB) notified the National Institute of Allergy and Infectious Disease (NIAD), the Biomedical Advanced Research and Development Authority (BARDA) and AstraZeneca that is was concerned that AstraZeneca included outdated information from their investigational trial, which may have provided an incomplete view of the efficacy of the data.
- *NEW* March 22: The NIH <u>announced</u> that the AstraZeneca COVID-19 vaccine candidate is well tolerated and protects against symptomatic COVID-19 disease.
- *NEW* March 8: The NIH <u>announced</u> the launch of third clinical trial to test blood clotting treatments for COVID-19 as part of the <u>Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)</u> initiative.
- *NEW* March 2: The NIH <u>announced</u> the suspension of a clinical trial evaluating the safety and effectiveness of COVID-19 convalescent plasma in patients with mild to moderate symptoms.
- *NEW* March 1: The NIH <u>announced</u> the launch of a study to assess the performance of usability of a smartphone app paired with the recently authorized Quidel QuickVue At-Home COVID-19 Test.
- **February 24:** The NIH <u>announced</u> study findings that people with COVID-19 antibodies have a low risk for future infection.
- **February 17:** The NIH <u>announced</u> the launch of a study that will evaluate remdesivir for COVID-19 in pregnancy women.
- **February 8:** The NIH <u>announced</u> the launch of a clinical trial to evaluate long-acting antibody therapy for individuals hospitalized with COVID-19.
- **January 29:** The NIH <u>announced</u> that the interim analysis of Phase 3 clinical data for the Janssen COVID-19 vaccines demonstrate that the candidate is 66 percent effective at preventing COVID-19 infection.
- **January 26:** The NIH <u>announced</u> the launch of <u>database</u> to track neurological symptoms associated with COVID-19.
- **January 5:** The NIH <u>announced</u> the launch of a Phase 2/3 clinical trial to evaluate a combination investigational monoclonal antibody therapy for treatment of hospitalized COVID-19 patients.

- **December 30:** The NIH <u>published</u> peer-review report on Moderna COVID-19 vaccine clinical effectiveness.
- **December 28:** The NIH <u>announced</u> that the Phase 3 trial of the Novavax investigational COVID-19 vaccine has launched.
- **December 16**: The NIH <u>announced</u> the launch of observational study to evaluate the short- and long-term outcomes of COVID-19 infection in children, including multisystem inflammatory syndrome in children (MIS-C).
- **December 11**: The NIH <u>announced</u> that baricitinib, an anti-inflammatory drug, and remdesivir, an antiviral, have reduced time to recovery for people hospitalized with COVID-19 in recent clinical trials.
- **December 7**: The NIH <u>announced</u> the launch of the <u>COVID-19 Testing Impact Calculator</u>, an online tool funded by the National Institute of Biomedical Imaging and Bioengineering that assists organizations on choosing a COVID-19 testing strategy that best suits their needs.
- **November 25**: The NIH <u>announced</u> the fourth iteration of the Adaptive COVID-19 Treatment Trial (ACTT-4), which will enroll up to 1,500 hospitalized COVID-19 patients to new treatment approaches.
- **November 20**: The NIH <u>awarded</u> \$45 million to expand the research network of the Rapid Acceleration of Diagnostics Underserved Population (RADx-UP) program by adding 20 new institutions and 7 states and territories.
- **November 16:** The NIH <u>announced</u> that the preliminary data from Moderna's Phase 3 COVID-19 vaccine trial demonstrates that the candidate (mRNA-1273) is safe and 94.5 percent effective (WHG client summary).
- **November 11:** The NIH <u>announced</u> the urgent need to develop drugs to treat COVID-19 patients early in the course of the infection.
- **November 9:** The NIH <u>announced</u> that hydroxychloroquine does not benefit adult hospitalized with COVID-19.
- October 30: The NIH <u>issued</u> a request for information (RFI) to gather public input on the NIH-Wide Strategic Plan for COVID-19 Research (WHG client <u>summary</u>).
- October 28: The NIH <u>announced</u> new research that indicates that biological pathway COVID-19 uses to spread throughout the body, which may provide insight in stopping the transmission of the virus.
- October 13: The NIH <u>announced</u> a new study aimed at determining if certain COVID-19 treatments warrant larger clinical trials.
- October 8: The NIH <u>announced</u> the launch of a clinical trial to test hyperimmune intravenous immunoglobin combined with remdesivir to treat COVID-19.

- October 6: The NIH <u>announced</u> a third round of awards to advanced new COVID-19 testing technologies through the Rapid Acceleration of Diagnostics (RADx) Initiative (WHG client <u>summary</u>).
- **September 30:** The National Institutes of Health (NIH) <u>awarded</u> \$239 million to improve COVID-19 testing for underserved and vulnerable populations, as part of the Rapid Acceleration of Diagnostics (RADx) Initiative Underserved Populations (RADx-UP) (WHG client <u>summary</u>).
- **September 29:** The NIH <u>announced</u> that initial Phase 1 trial results from the Moderna vaccine candidate demonstrate that the vaccine is well-tolerated and generates a strong immune response in older adults (WHG client <u>summary</u>).
- **September 23:** The NIH <u>announced</u> the launch of the fourth Phase 3 clinical trial for a COVID-19 vaccine candidate sponsored by Janssen (WHG client summary).
- **September 22:** The NIH <u>announced</u> the expansion of clinical trials to evaluate convalescent plasma as treatment for hospitalized COVID-19 patients (WHG client summary).
- **September 16:** The NIH <u>awarded</u> \$12 million for outreach and engagement efforts in ethnic and racial minority communities disproportionately impacted by the COVID-19 pandemic (WHG client <u>summary</u>).
- **September 15:** The NIH <u>announced</u> seven contracts to companies and academic institutions to develop digital health solutions to help address the COVID-19 pandemic (WHG client <u>summary</u>).
- **September 14:** The NIH <u>released</u> study finds that reveal that people with substance use disorders are more susceptible to COVID-19 and its complications.
- **September 1:** The NIH <u>announced</u> the launch of a study to track the prevalence and impact of COVID-19 among pregnant women in low and middle-income countries.
- **August 31:** The NIH <u>announced</u> the launch of a Phase 3 clinical trial of AstraZeneca's COVID-19 vaccine candidate in the United States. The trial will enroll 30,000 adult volunteers at 80 sites.
- August 28: The National Institute of Allergy and Infectious Diseases (NIAID) announced the
 establishment of the Centers for Research in Emerging Infectious Diseases (WHG client
 summary).
- August 7: The NIH announced several funding opportunities through its Rapid Acceleration of Diagnostics Radical (RADx-rad) initiative to support the development of novel, non-traditional approaches to identify COVID-19 (WHG client <u>summary</u>).
- **August 7:** The NIH <u>announced</u> a <u>funding opportunity</u> to identify children at risk for developing Multisystem Inflammatory Syndrome in children (MIS-C), thought to be a serve complication of COVID-19 (WHG client <u>summary</u>).

- August 5: NIH <u>announced</u> the launch of the Medical Imaging and Data Resource Center (MIDRC), that aims to leverage artificial intelligence and medical imaging for COVID-19 diagnosis, treatment, monitoring.
- **August 5:** NIH <u>announced</u> that the NIH-Moderna investigational vaccine, mRNA-1273, has protected mice from COVID-19 infection.
- **July 31:** The NIH, through its Rapid Acceleration of Diagnostics (RADx) Initiative, <u>announced</u> \$248.7 million in awards for seven new COVID-19 diagnostic technologies (WHG client <u>summary</u>).
- **July 27:** The NIH <u>announced</u> that the Operation Warp Speed sponsored COVID-19 vaccine, Moderna's mRNA-1273, has begun Phase 3 clinical trial. The trial is expected to enroll 30,000 adult volunteers (WHG client summary).
- **July 22:** The NIH <u>announced</u> that the Rapid Acceleration of Diagnostics (RADx) program has outlined a framework to manufacture 6 million diagnostic tests per day by the end of 2020. (WHG client summary).
- **July 14:** The NIH <u>announced</u> that an experimental COVID-19 vaccine has generated an immune response. (WHG client <u>summary</u>).
- **July 8:** The NIH <u>announced</u> the launch of the COVID-19 Prevention Trials Network (COVPN), a clinical trials network that aims to enroll thousands of volunteers in large-scale clinical trials testing investigational vaccines and monoclonal antibodies (WHG client <u>summary</u>).
- **July 1:** The NIH <u>announced</u> that the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Vaccines Working Group assessed considerations for using controlled human infection models (CHIMs) to support vaccine development.
- **June 20:** The NIH <u>announced</u> that it is halting the clinical trial of hydroxychloroquine. The agency's data and safety monitoring board determined that while hydroxychloroquine does not cause harm, the drug is unlikely to be beneficial for hospitalized COVID-19 patients.
- **June 16:** The NIH's *All of Us* Program <u>announced</u> the launch of COVID-19 research initiatives, which will leverage its participant base to develop new knowledge through antibody testing, a survey on the pandemic's impact, and the collection of electronic health information.
- **June 15:** The NIH National Center for Advancing Translational Science (NCATS) <u>launched</u> the National COVID Cohort Collaborative (N3C), a centralized and secure platform to store and study vast amounts of medical record data from people diagnosed with COVID-19 across the country (WHG client <u>summary</u>).
- **June 10:** NIH <u>announced</u> the launch of a study to examine drugs prescribed to children with COVID-19.
- May 22: The NIH <u>announced</u> that peer-reviewed data demonstrates that remdesivir improves recovery time for patients with COVID-19, especially among those with severe cases (WHG client <u>summary</u>).

- 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.
- May 14: The NIH <u>announced</u> 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 summary).
- **April 21:** The NIH <u>announced</u> the first <u>treatment guidelines for COVID-19 patients</u>, intended for healthcare providers (WHG client summary)
- **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 <u>summary</u>)
- **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 <u>guidance</u> 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

- **July 14**: The IRS issued a <u>notice</u> that extends the deadline for tax-exempt hospitals to conduct a community health needs assessment and adopt an implementation strategy to meet the needs identified. The deadline is now December 31, 2020.
- **June 19:** The IRS released (<u>press release</u>) a <u>notice</u> that details how retirement plan participants affected by COVID-19 can take advantage of the CARES Act provisions providing enhanced access to plan distributions and plan loans.
- **June 17**: The IRS <u>highlighted</u> changes to health care spending that provide greater flexibility under the CARES Act.
- **June 16**: The IRS <u>announced</u> it had alerted nursing home and other care facilities that Economic Impact Payments (EIPs) generally belong to the recipients, not the organizations providing the care.
- **June 12**: Treasury and the IRS issued (<u>press release</u>) a <u>notice</u> that provides tax relief for certain taxpayers (e.g., businesses and investors) affected by the COVID-19 pandemic who are involved in new markets tax credit transactions.
- **June 11**: The IRS issued (<u>press release</u>) <u>guidance</u> on employer leave-based donation programs that aid victims of the COVID-19 pandemic.
- May 26: Treasury and the IRS issued (<u>press release</u>) <u>final regulations</u> clarifying the reporting requirements that apply to tax-exempt organizations.
- May 22: Treasury and the IRS <u>released</u> updated state-by-state figures for Economic Impact Payments.
- 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 summary).

- 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 <u>here</u>.
- 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)

- **February 24:** USDA released a <u>fact sheet</u> describing the actions it is taking to contain the COVID-19 pandemic.
- **February 17:** USDA released a <u>fact sheet</u> describing the actions it is taking to contain the COVID-19 pandemic.
- **January 4:** USDA announced it will purchase an additional \$1.5 billion worth of food for nationwide distribution through the Farmers to Families Food Box Program.
- **December 31:** USDA announced that it approved Maine 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 49 plus the District of Columbia. 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.
- October 23: USDA <u>announced</u> it has authorized \$500 million for a fourth round of purchases for the USDA Farmers to Families Food Box Program. USDA is issuing solicitations for the fourth round to existing Basic Ordering Agreement (BOA) holders and expects to award contracts by Oct. 30 for deliveries of food boxes from Nov. 1 through Dec. 31, 2020.

- October 9: USDA <u>announced</u> that it extended waiver flexibilities to allow free meals to continue to be available to all children throughout the entire 2020-2021 school year.
- **September 29:** USDA <u>announced</u> that more than 100 million food boxes have been distributed in support of American farmers and families affected by the COVID-19 pandemic through the agency's <u>Farmers to Families Food Box Program</u>.
- **September 21:** USDA indicated that it has leveraged its ongoing emergency waiver authority granted under the Families First Coronavirus Response Act (FFCRA) to extend flexibilities for the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Without the extension, the flexibilities would have expired on September 30. Instead, they are now in place for the duration of the public health emergency (PHE). (WHG client <u>summary</u>).
- **August 31:** FNS <u>announced</u> that it would extend several nationwide school meal waivers through the end of the 2020 calendar year, "or until available funding runs out." (WHG client <u>summary</u>).
- August 20: Bobby Scott (D-VA), Chairman of the House Committee on Education and Labor, published USDA Secretary Perdue's <u>response</u> to his August 14 request regarding the extension of school meal waivers. The Secretary states that, "the scope of this request is beyond what USDA currently has the authority to implement and would be closer to a universal school meals program which Congress has not authorized or funded." (WHG client <u>summary</u>).
- August 19: USDA <u>announced</u> that Idaho was the 50th and final 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.
- **August 17:** Chairman of the Senate Committee on Agriculture, Sen. Pat Roberts (R-KS), sent a <u>letter</u> to USDA Secretary Sonny Perdue urging the Department to continue providing school meal and child nutrition program flexibilities. (WHG client <u>summary</u>).
- August 14: Democrats Bobby Scott (D-VA), Chairman of the House Committee on Education
 and Labor, and Sen. Debbie Stabenow (D-MI), Ranking Member of the Senate Committee on
 Agriculture, sent a <u>letter</u> to USDA Secretary Sonny Perdue encouraging his agency to continue
 making full use of FFCRA flexibilities to provide school meals to children impacted by COVID19 school closures. (WHG client <u>summary</u>).
- **July 27:** USDA <u>announced</u> a third round of <u>Farmers to Families Food Box Program</u> purchases with distributions to occur beginning by September 1 with completion by October 31, 2020. The purchases will spend the balance of \$3 billion authorized for the program.
- **July 23:** USDA <u>announced</u> that it approved Arkansas and Hawaii 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 48 plus the District of Columbia. 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.

- **July 20:** USDA <u>announced</u> that it approved North Dakota to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **July 17:** USDA <u>announced</u> additional food for families in the Food Distribution Program on Indian Reservations (FDPIR) in response to the COVID-19 pandemic. The increased food assistance will temporarily supplement the monthly food package FDPIR households currently receive.
- **July 16:** USDA <u>announced</u> that its Meals to You partnership has delivered more than 28.5 million meals to the doorsteps of low-income kids in rural communities across America during the COVID-19 health crisis.
- **July 10:** USDA <u>announced</u> that Nevada was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **July 9:** USDA <u>announced</u> that Utah was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **June 29:** USDA <u>announced</u> the award of \$12.1 million in Farm to School Grants to 159 grantees to help bring fresh, local foods into schools and foster economic opportunity for America's farmers over the next school year.
- **June 26:** USDA <u>announced</u> that Oklahoma and Montana were approved to operate Pandemic Electronic Benefit Transfer (EBT).
- June 25: USDA <u>announced</u> the extension of a range of nationwide flexibilities to ensure America's children receive the nutritious food they need throughout the upcoming school year. Specifically, nationwide waivers of meal pattern and timing requirements, congregate feeding requirements, and allowing for parent/guardian pick-up will remain in effect through June 30, 2021in the School Breakfast Program (SBP), National School Lunch Program (NSLP), and Child and Adult Care Food Program (CACFP).
- **June 23:** USDA <u>announced</u> that the <u>Farmers to Families Food Box Program</u> has distributed more than 20 million food boxes in support of American farmers and families affected by the COVID-19 pandemic.
- **June 23:** USDA <u>announced</u> that it approved Kansas to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **June 22:** USDA <u>announced</u> that South Dakota was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **June 18:** USDA <u>announced</u> that Nebraska and South Carolina were approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **June 16:** USDA <u>announced</u> that it approved South Carolina and Utah to participate in a pilot program to provide online purchasing of food for SNAP recipients.

- **June 10:** USDA <u>announced</u> a nationwide extension of area eligibility waivers for USDA's child nutrition programs. This waiver allows local partners the ability to continue serving free meals to all children regardless of where they live for the remainder of the summer (though August 31).
- **June 10:** USDA <u>announced</u> that the U.S. Virgin Islands were approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **June 10:** USDA announced that it approved <u>Delaware</u> and <u>Mississippi</u> to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **June 5:** USDA <u>announced</u> that Georgia and Iowa were approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **June 5:** USDA <u>announced</u> that it approved South Dakota to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **June 5:** USDA <u>announced</u> that Alaska was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **June 4:** USDA <u>announced</u> that the <u>Farmers to Families Food Box Program</u> has distributed more than five million food boxes in support of American farmers and families affected by the COVID-19 pandemic.
- **June 3:** USDA <u>announced</u> that it approved New Hampshire to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **June 2:** USDA <u>announced</u> that Mississippi was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 28: USDA <u>announced</u> that Hawaii was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 28: USDA <u>announced</u> that it approved Florida and Minnesota to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- May 26: USDA <u>announced</u> that Washington was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 22: USDA <u>announced</u> that Arkansas was approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 20: USDA <u>announced</u> that Kentucky, Tennessee, and DC were approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 20: USDA <u>announced</u> 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.
- May 18: USDA <u>announced</u> that Colorado, Missouri, and Wyoming were approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 15: USDA <u>announced</u> the extension of three nationwide school meal waivers, giving child nutrition program operators the flexibility they need to continue to feed children during the COVID-19 pandemic, including: non-congregate feeding waivers; parent pickup waivers; and meal time waivers.
- May 14: USDA <u>announced</u> that it approved Wyoming to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **May 14:** USDA <u>announced</u> that New Hampshire was the 20th state approved to operate Pandemic Electronic Benefit Transfer (EBT).
- May 12: USDA <u>announced</u> that Ohio is the 19th state approved to operate Pandemic Electronic Benefit Transfer (EBT).
- 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).
- 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.
- May 8: USDA <u>announced</u> that it approved Rhode Island to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- May 7: USDA <u>announced</u> that it approved New Mexico to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- 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).
- May 6: USDA <u>announced</u> that it approved Colorado to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- 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.
- May 5: USDA announced a major expansion of Meals to You, USDA's innovative partnership 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.

- 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.
- May 1: USDA <u>announced</u> that Delaware and Oregon were the 13th and 14th states approved to operate Pandemic Electronic Benefit Transfer (EBT).
- 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).
- **April 27:** USDA <u>announced</u> that Kansas and Virginia were the ninth and tenth states approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **April 24:** USDA <u>announced</u> that it approved requests from California and Connecticut and Vermont (<u>here</u>) to participate in a pilot program to provide online purchasing of food for SNAP recipients.
- **April 23:** USDA <u>announced</u> that Wisconsin was the eighth state approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **April 22:** USDA <u>announced</u> that Alabama was the seventh state approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **April 22:** USDA <u>announced</u> 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.
- **April 20:** USDA <u>announced</u> that Arizona and Illinois have been approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **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.
- **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 <u>announced</u> that North Carolina and Massachusetts have been approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **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.

- **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).
- 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.
- **April 9:** USDA <u>announced</u> that Michigan is the first state approved to operate Pandemic Electronic Benefit Transfer (EBT).
- **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.
- 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 summary).
- 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 <u>here</u>.
- 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 <u>summary</u>).

DEPARTMENT OF JUSTICE

• **June 30:** The DOJ issued a <u>warning</u> that flyers and postings citing the Americans with Disabilities Act and exempting individuals with disabilities from complying with face masks requirements are fraudulent.

- April 13: The DOJ and the FTC issued a joint statement 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* March 29: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$4.47 billion in vaccination expenses and is continuing to open new federal vaccination centers.
- *NEW* March 25: FEMA amended all major disaster declarations for COVID-19 to pay 100% of total eligible costs (up from 75%) between Jan. 20, 2020 and Sept. 30, 2021, per an executive order issued Feb. 2.
- *NEW* March 24: FEMA <u>issued</u> a new interim policy on funeral assistance related to COVID-19 for individuals and households. The agency notes it will pay funeral costs up to \$9,000 per COVID-19 death with a maximum of \$35,500 allowed per applicant.
- *NEW* March 22: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$4.39 billion in vaccination expenses.
- *NEW* March 19: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency will soon open federal pilot community vaccination centers in Atlanta and Detroit.

- *NEW* March 17: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$4.38 billion in vaccination expenses.
- *NEW* March 9: FEMA <u>announced</u> that it has established a Civil Rights Advisory Group to evaluate FEMA's COVID-19 vaccination policies, practices, strategies, and plans to ensure equitable vaccine access and administration.
- *NEW* March 8: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$4.24 billion in vaccination expenses.
- *NEW* March 5: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$4.13 billion in vaccination expenses and is operating more than 500 community and 70 mobile vaccination centers across the nation. Additionally, beginning next week, the weekly vaccine allocation to states, tribes, and territories will increase to 15.2 million doses.
- *NEW* March 3: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency is opening new pilot community vaccination centers at sites in Florida and New York and now has 55 mobile vaccination centers across the nation.
- *NEW* March 2: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$4.02 billion in vaccination expenses and has established or expanded more than 450 community and 47 mobile vaccination centers across the nation.
- *NEW* March 1: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes that effective this week, the weekly vaccine supply to states will increase to 14.5 million doses.
- *NEW* February 26: FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$3.97 billion in vaccination expenses and has established or expanded more than 440 community vaccination centers across the nation.
- **February 16:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$3.38 billion in vaccination expenses to states, tribes, territories, and Washington, D.C.
- **February 12:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$3.22 billion in vaccination expenses.
- **February 11:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has deployed 1,154 staff across the country.

- **February 10:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency is seeking proposals to contract medical workers to help staff both federally supported and community vaccine centers throughout the country.
- **February 9:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has now provided more than \$3.15 billion in vaccination expenses and deployed 752 incident management and 317 incident support staff.
- **February 8:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes the agency has provided more than \$2.29 billion in vaccination expenses.
- **February 5:** FEMA released <u>guidance</u> for providing federal support to state, tribal and territorial Community Vaccination Centers.
- **February 5:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support.
- **February 4:** FEMA <u>issued</u> a COVID-19 response update describing its vaccine distribution support. The report notes that the agency has deployed 449 staff and is operating 130 federally supported sites across the country.
- **February 3:** FEMA <u>released</u> a COVID-19 response update describing its vaccine distribution support. It notes that President Biden has directed the agency to retroactively reimburse states for 100 percent of the costs for eligible emergency protective measures.
- **February 1:** FEMA <u>released</u> a COVID-19 response update describing its vaccine distribution support, detailing the distribution of more than \$1 million to states within the last 48 hours.
- **January 28:** FEMA issued a <u>press release</u> with updated information about its role in supporting vaccine distribution as part of the COVID-19 response.
- **January 27:** FEMA released a <u>fact sheet</u> with information for exporters with a surplus of medical supplies and equipment.
- **January 26:** FEMA <u>announced</u> it has released nearly \$1 billion in funding through its Public Assistance grant program to support vaccinations.
- **January 25:** FEMA issued a <u>press release</u> detailing how it is supporting vaccine distribution under the Biden administration.
- **January 15:** FEMA published a <u>fact sheet</u> about a voluntary agreement established in August under the Defense Production Act that allows the federal government and the private sector to share more information than is typically allowed under antitrust laws.
- **December 31:** FEMA extended its temporary final rule on domestic PPE prioritization.
- **December 14:** FEMA issued a <u>proposed rule</u> to revise the "Estimated cost of the assistance," which is one of the factors FEMA's Public Assistance Program considers when evaluating

requests from states for major disaster declarations and making recommendations to the President (WHG client summary).

- **November 23:** FEMA updated <u>guidance</u> advising state, tribal, and territorial governments about how to submit coronavirus-related medical staffing requests.
- **November 16:** FEMA released <u>guidance</u> advising state, tribal, and territorial governments about how to submit coronavirus-related medical staffing requests.
- October 23: FEMA released a <u>white paper</u>, focused on the mid-Atlantic region, that describes COVID-19's impact on the human and social services sector.
- **September 2:** FEMA <u>released</u> an interim policy to clarify eligible work under the Public Assistance program for the COVID-19 pandemic.
- **August 13:** FEMA published a <u>fact sheet</u> detailing the process and eligibility for lost wage supplemental payment assistance pursuant to the President's <u>memo</u>.
- August 10: FEMA published a fact sheet about the extension of its temporary final rule.
- **August 6:** FEMA <u>extended</u> its temporary final rule on domestic PPE prioritization and made changes to the list of applicable products (WHG client summary).
- **July 21:** FEMA released <u>FAQs</u> about the reconstitution of operations or "reopening" after the coronavirus.
- **July 20:** The FEMA Administrator sent a <u>letter</u> urging Emergency Managers to consider supporting Emergency Management Assistance Compact (EMAC) requests from Arizona, California, Florida, Louisiana, and Texas for medical professionals.
- **July 6:** FEMA <u>updated</u> guidance regarding its <u>temporary final rule</u>, issued in April, to distribute certain scarce PPE for domestic use.
- **July 1:** FEMA <u>released</u> a fact sheet detailing how the agency has coordinated COVID-19 Public Assistance Program funding and other federal funds to state, local, tribal, and territorial government entities and certain private nonprofit organizations to address the effects of the pandemic.
- **July 1:** FEMA issued a <u>memo</u> clarifying the facility eligibility requirements for private nonprofit (PNP) entities, and waiving the primary use and primary ownership policies normally applicable to PNP entities regarding mixed-use facilities and facilities used by multiple entities.
- **June 18:** FEMA <u>announced</u> it is phasing out Project Airbridge.
- **June 11:** FEMA <u>released</u> state-by-state data on COVID-19 response, including the distribution of PPE and ventilators, federal support funding amounts, and reopening phase.
- **June 10:** FEMA released (<u>press release</u>) <u>guidance</u> for providing mass care during a pandemic that includes information on sheltering, feeding, evacuation and the federal resource request process.

- **June 8:** FEMA announced that the Emergency Food and Shelter Program (EFSP) National Board will disburse \$320 million to organizations that provide food, shelter, and supportive services to people with economic emergencies. Congress appropriated \$200 million of this funding via the CARES Act. Award amounts by jurisdiction and state are available here.
- **June 5:** FEMA released a <u>fact sheet</u> about the historic preservation compliance procedures for the Coronavirus pandemic emergency.
- **June 5:** FEMA <u>released</u> state-by-state data on COVID-19 response, including the distribution of PPE and ventilators, federal support funding amounts, and reopening phase.
- **June 1:** The FEMA Administrator sent a <u>letter</u> to emergency managers across the country alerting them to the outlook for hurricane season and providing resources for hurricane response during the COVID-19 pandemic.
- **May 29:** FEMA <u>released</u> state-by-state data on COVID-19 response, including the distribution of PPE and ventilators, federal support funding amounts, and reopening phase.
- May 26: FEMA released a <u>fact sheet</u> detailing the distribution of non-contact, infrared
 thermometers to support the phased reopening of workplaces across the country. Allocation
 amounts are based on the estimated number of private workplaces in each state with 50 or more
 employees (see fact sheet for number of thermometers by state and territory).
- May 22: FEMA <u>released</u> state-by-state data on COVID-19 response, including the distribution of personal PPE and ventilators, federal support funding amounts, and reopening phase.
- 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.
- 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 summary).
- **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 released 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 <u>summary</u>).
- **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 Program</u> (WHG client <u>summary</u>).
- 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 here.

- **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

- November 18: ACL <u>updated</u> its COVID-19 <u>resources</u>.
- **September 14:** ACL updated its COVID-19 resources.
- August 5: ACL updated its COVID-19 resources.
- **July 14:** ACL updated its COVID-19 resources.
- **July 6:** ACL updated its COVID-19 resources.
- **June 26:** ACL updated its COVID-19 resources.
- **June 16:** ACL updated its COVID-19 resources.
- **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 <u>summary</u>).
- **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

- August 10: SAMHSA <u>updated</u> training and technical assistance related to COVID-19.
- August 3: SAMHSA <u>updated</u> training and technical assistance related to COVID-19.
- July 27: SAMHSA updated training and technical assistance related to COVID-19.
- **July 1:** CMS and SAMHSA <u>issued</u> guidance on leveraging existing health management programs to provide mental health and substance use disorder resources during the COVID-19 public health emergency.
- **June 25:** SAMHSA <u>released</u> training and technical assistance related to COVID-19.
- **May 13:** SAMHSA <u>announced</u> a funding opportunity for COVID-19 emergency response suicide prevention (WHG client summary).
- **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 summary).
- 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 <u>published</u> 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.

- January 8: SBA <u>announced</u> the re-opening of the Paycheck Protection Program for new borrowers and certain existing PPP borrowers on January 11 as well as the issuance of <u>guidance</u> on accessing capital for minority, underserved, veteran, and women-owned businesses, <u>interim final rule</u> on new PPP loans, and an <u>interim final rule</u> on second draw PPP loans.
- **July 11:** SBA <u>announced</u> the conclusion of the Economic Injury Disaster Loan (EIDL) Advance program. SBA has fully allocated the \$20 million appropriated by Congress and will stop making EIDL Advances to new applicants.
- **July 6:** SBA, in consultation with the Treasury Department, <u>released</u> loan-level data regarding the loans made under the Paycheck Protection Program. Data is available <u>here</u>.
- **June 19:** SBA and the Department of Treasury <u>announced</u> that details on PPP borrowers that receive loans above \$150,000 will be made publicly available. Details include business names, addresses, NAICS codes, zip codes, business type, demographic data, non-profit information, jobs supported, and loan amount ranges (WHG client <u>summary</u>).
- **June 18:** SBA issued an interim final rule to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance on eligibility requirements relating to applicants with past felony convictions (WHG client <u>summary</u>).
- **June 17:** SBA, in consultation with the Department of Treasury, <u>released</u> a revised "borrower-friendly" Paycheck Protection Program (PPP) loan forgiveness application.
- May 28: SBA issued an interim final rule to supplement previously posted interim final rules on the Paycheck Protection Program (PPP) with additional guidance on loan forgiveness and loan review procedures and related borrower and lender responsibilities (WHG client summary).
- 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>).
- 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).
- May 15: SBA <u>released</u> the <u>Paycheck Protection Program Loan Forgiveness Instructions and Application</u> for borrowers (WHG client <u>summary</u>).

- 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 <u>summary</u>).
- May 1: The 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 PPP (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 summary).
- **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 summary).

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* March 29: The White House <u>announced</u> new actions to increase COVID-19 vaccinations. The Administration anticipates that by April 19, 90 percent of adults in the U.S. will be eligible for vaccination and 90 percent will be within five miles of a vaccination site. (WHG client <u>summary</u>).
- *NEW* March 25: The White House <u>announced</u> it is distributing \$10 billion to expand access to COVID-19 vaccines, with a focus on improving vaccine confidence in high-risk communities. (WHG client <u>summary</u>).

- *NEW* March 11: The White House <u>announced</u> that all adult Americans will be eligible to receive a COVID-19 vaccination by May 1, 2021 (WHG client <u>summary</u>).
- **February 24**: President Biden <u>announced</u> new actions to deliver masks to communities disproportionately impacted by the COVID-19 pandemic (WHG client <u>summary</u>).
- **February 17**: The White House <u>announced</u> new actions the administration is taking to expand and improve COVID-19 testing (WHG client <u>summary</u>).
- **February 9:** The Biden-Harris administration announced in a <u>fact sheet</u> a set of new steps it is taking to expand vaccine distribution and supply in the U.S. We outline these initiatives below (WHG client <u>summary</u>).
- **February 2:** President Biden <u>announced</u> the several actions aimed at increasing COVID-19 vaccinations and federal support to states (WHG client <u>summary</u>).
- **January 21:** President Joe Biden unveiled his administration's "National Strategy for the COVID-19 Response and Pandemic Preparedness," a roadmap to guide and centralize the federal government's response to the pandemic (WHG client summary).
- **January 21:** President Biden issued an <u>executive order on requiring mask-wearing</u> and an <u>executive order organizing an effective COVID-19 response effort.</u>
- October 5: President Trump released an <u>Executive Order</u> (EO) to increase support for mental health needs, citing an increased need as COVID-related shutdowns continue across the country (fact sheet). (WHG client summary).
- **September 29:** President Donald J. Trump faced former Vice President and Democratic presidential candidate Joseph R. Biden in the first of three 2020 general election debates. The candidates each addressed their records and plans for management of the COVID-19 pandemic. (WHG client <u>summary</u>).
- **September 16:** The Trump Administration <u>announced</u> its plan for distributing and administering a COVID-19 vaccine once one becomes available, which include a <u>Report to Congress</u> on its overall strategy, along with a complementary <u>operational playbook</u> for states (WHG client <u>summary</u>).
- 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 summary)
- **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 <u>"Guidelines for Opening Up America Again"</u> guidance for states to reopen their economies in phases (<u>press release</u>; <u>fact sheet</u>) (WHG client <u>summary</u>).
- 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 <u>N-95 respirators</u>.
- 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 <u>summary</u>).
- **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 <u>summary</u>).
- 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 <u>guidelines</u> 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 summary).

CONGRESSIONAL RESPONSE

Legislation

- *NEW* March 11: President Joe Biden <u>signed</u> the American Rescue Plan Act of 2021 (<u>P.L. 117-2</u>) into law. Congress approved the 1.9 trillion COVID-19 relief package along party lines <u>220-211</u> in the House and <u>50-49</u> in the Senate using the budget reconciliation process. (WHG client <u>summary</u>).
- *NEW* March 4: The Senate adopted a motion to proceed to consideration of the American Rescue Plan Act of 2021 (H.R. 1319) by a 51-50 vote, with Vice President Kamala Harris breaking the tie. (WHF client summary).
- **February 22:** House Budget Committee approved the American Rescue Plan Act of 2021.
- **February 12:** House committees marked up legislation under the reconciliation instructions adopted in the Fiscal Year (FY) 2021 Joint <u>Budget</u> Resolution (<u>S.Con.Res.5</u>) a key step to pass President Joe Biden's \$1.9 trillion <u>American Rescue Plan</u> through budget reconciliation (WHG client <u>summary</u>).
- **December 21:** Congress passed the fiscal year (FY) 2021 <u>omnibus spending bill</u>, which includes the <u>Emergency Coronavirus Relief Act</u>.
- October 21: The Senate failed to pass a motion to invoke cloture on the GOP targeted COVID-19 relief package championed by Senate Majority Leader Mitch McConnell (R-KY). Leader McConnell lacked the support of 60 members to overcome the procedural hurdle needed to hold a final vote on the package. The cloture measure failed by a 51-44 vote along party lines. (WHG client summary).
- **September 28:** House Democrats released an updated version of the Heroes Act a \$2.2 trillion package to provide additional coronavirus relief (<u>press release</u>; <u>legislative text</u>; <u>summary</u>; <u>section-by-section</u>). (WHG client <u>summary</u>).

- **September 16:** The Problem Solvers Caucus, a 50-member bipartisan group in the House, released its "March To Common Ground" framework a plan intended to "break the gridlock" in negotiations between Democrats and Republicans over a COVID-19 relief package. (WHG client summary).
- **September 8:** Senate Majority Leader Mitch McConnell (R-KY) unveiled a scaled-back coronavirus relief package containing approximately \$500 billion in federal aid focused on health care, education, and the economy (**legislative text**). (WHG client summary).
- **July 27:** Senate Republicans unveiled the Health, Economic Assistance, Liability Protection, and Schools (HEALS) Act a package intended to provide additional coronavirus relief, support the federal government's coronavirus response, help businesses and schools reopen safely, and stimulate the economy. The package is a compilation of individual bills authored by Republican Committee leaders. (WHG client summary).
- **June 9:** Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) released a <u>white paper</u>, "Preparing for the Next Pandemic" a starting point for a legislative package to bolster the federal government's public health infrastructure and capacity (WHG client <u>summary</u>).
- **June 6:** President Trump signed into law the Paycheck Protection Program Flexibility Act of 2020 (<u>H.R. 7010</u>), which makes several reforms to the Small Business Administration's (SBA) <u>Paycheck Protection Program (PPP)</u> (WHG client <u>summary</u>).
- May 29: The House passed the TRUTH Act (<u>H.R. 6782</u>) (269-147) and the Paycheck Protection Program Flexibility Act of 2020 (H.R. 7010) (417-1) (WHG client summary).
- May 27: Reps. Diana DeGette (D-CO) and Larry Bucshon (R-IN) introduced <u>Diagnostic Testing</u>
 for <u>Public Health Labs Act of 2020</u> and <u>Rapid Testing for Communities Act of 2020</u>, bipartisan
 legislation intended to expand coronavirus testing capacity and accessibility (WHG client
 summary).
- 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 summary).
- 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)
 <u>introduced</u> the Pandemic Response and Opportunity Through National Service Act (WHG client
 <u>summary</u>).

- 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 <u>summary</u>).
- **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 summary).
- 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 summary).
- 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. 6201</u>) 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 <u>summary</u>).
- March 10: House Education and Labor Committee Chairman Bobby Scott (D-VA), Rep. Donna Shalala (D-FL), and Committee Democrats introduced the COVID-19 Worker Protection Act of 2020 (H.R. 6139). The bill was incorporated into introduced version of H.R. 6201, but was not included in the final version approved by the House. (WHG client summary).
- **March 6:** The President signed the \$8.3 billion emergency supplemental appropriation bill to address the COVID-19 outbreak into law. (WHG client summary).
- March 5: The Senate <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* March 17: The House E&C Subcommittee on Oversight and Investigations <u>convened</u> a hearing to examine the Biden Administration's efforts to increase COVID-19 vaccination rates. (WHG client <u>summary</u>).
- *NEW* March 2: The House E&C Subcommittee on Health <u>convened</u> a hearing to discuss the future of telehealth reform in light of the recent, pandemic-driven expansions (WHG client <u>summary</u>).

- **February 24:** The House Appropriations Subcommittee on LHHS <u>convened</u> a hearing to examine how emergency supplemental appropriations have been used to bolster the federal, state, and local response to the COVID-19 pandemic and discuss ongoing and long-term challenges (WHG client summary).
- **February 3:** The House Energy and Commerce Subcommittee on Health <u>convened</u> a hearing to discuss current and future needs for ramping up on COVID-19 vaccines, testing, and the medical supply chain (WHG client <u>summary</u>).
- **February 2:** The House Energy and Commerce Subcommittee on Oversight and Investigations <u>convened</u> a hearing to examine state perspectives on the COVID-19 vaccine rollout and distribution (WHG client <u>summary</u>).
- October 20: The House Ways & Means Subcommittee on Oversight <u>convened</u> a hearing to examine health insurance coverage and the Administration's efforts to undermine the Affordable Care Act (WHG client <u>summary</u>).
- October 2: The House Select Subcommittee on the Coronavirus Crisis <u>convened</u> a hearing with Department of Health and Human Services (HHS) Secretary Alex Azar to examine the Administration's political interference in the COVID-19 pandemic response (WHG client summary).
- **September 30:** The House Energy and Commerce (E&C) Subcommittee on Oversight and Investigations (O&I) convened a <u>hearing</u> to examine the safety and effectiveness of, access to, and the public's trust in prospective COVID-19 vaccines. (WHG client <u>summary</u>).
- **September 24:** At its September public meeting, MACPAC convened sessions on Medicaid provider relief funding for COVID-19 and Medicaid's response to COVID-19. All WHG MACPAC session summaries are available here.
- **September 23:** The House Education and Labor Committee held a virtual briefing to examine the impact of the COVID-19 pandemic on child hunger and what the federal government can do to address the current child hunger crisis. (WHG client <u>summary</u>).
- **September 23:** The Senate HELP Committee convened a <u>hearing</u> to examine the Trump Administration's COVID-19 response efforts (WHG client summary).
- **September 16:** The House Select Subcommittee on the Coronavirus Crisis Chairman James Clyburn (D-SC) sent a letter to Vice President Mike Pence and Coronavirus Response Coordinator Dr. Deborah Birx, expressing concerns that the White House Coronavirus Task Force, under political pressure, weakened science-based public health recommendations (press release; letter). (WHG client summary).
- **September 16:** The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies convened a <u>hearing</u> to examine the Trump Administration's COVID-19 response efforts (WHG client summary).

- **September 9:** The Senate Health, Education, Labor & Pensions (HELP) Committee convened a <u>hearing</u> to examine the Administration's efforts to develop a COVID-19 vaccine and increase uptake of regularly scheduled vaccines (WHG client <u>summary</u>).
- **September 4:** At its September public meeting, MedPAC convened sessions on the impact of the Coronavirus pandemic on Medicare and Medicare providers and Medicare coverage for vaccines. All WHG MedPAC session summaries available here.
- **July 31:** The House Select Subcommittee on the Coronavirus Crisis convened a <u>hearing</u> to examine the urgent need for a national comprehensive plan to address the coronavirus pandemic (WHG client <u>summary</u>).
- **July 30:** The Senate Finance Committee <u>convened</u> a two-part hearing on protecting the reliability of the medical supply chain during the COVID-19 pandemic (WHG client summary).
- July 21: Reps. Katie Porter (D-CA) and Raja Krishnamoorthi (D-IL) sent a <u>letter</u> to HHS and the Biomedical Advanced Research Development Authority (BARDA) regarding "the lack of investment" in clinical trials and research on preventive COVID-19 immune globulin (COVID-IG) injections. (WHG client <u>summary</u>).
- **July 21:** The House Energy and Commerce Subcommittee on Oversight and Investigations <u>convened</u> a hearing to examine the COVID-19 vaccine development process (WHG client <u>summary</u>).
- **July 9:** Senate Health, Education, Labor and Pensions (HELP) Committee Ranking Member Patty Murray (D-WA) released a new <u>report</u>, "A Nation in Crisis: The Consequences of Federal Leadership Failures on the COVID-19 Diagnostic Testing System" (WHG client <u>summary</u>).
- **June 30:** The Senate Committee on Health, Education, Labor and Pensions (HELP) <u>convened</u> a hearing to discuss the necessary steps to safely reopen schools and the economy (WHG client summary).
- **June 23:** The House Committee on Energy and Commerce <u>convened</u> a hearing to discuss the federal government's response to the COVID-19 pandemic (WHG client <u>summary</u>).
- **June 22:** The House Education and Labor Committee convened a <u>hearing</u> to discuss how Congress can address racial inequities exacerbated by COVID-19 in education, health, and the workforce (WHG client <u>summary</u>).
- **June 11:** Senate Finance Committee Chairman Chuck Grassley (R-IA) and Ranking Member Ron Wyden (D-OR) wrote to Health and Human Services (HHS) Secretary Alex Azar, urging the Department to establish a comprehensive public database of coronavirus relief funds distributed to health care providers (press release; letter) (WHG client summary).
- **June 9:** The Senate Committee on Homeland Security and Governmental Affairs <u>convened</u> a hearing to examine the federal government's procurement and distribution of medical supplies during the COVID-19 pandemic (WHG client <u>summary</u>).

- **June 8:** The House Energy and Commerce Committee and Ways and Means Committee Chairs sent a letter to CMS, urging the agency to stop nursing facilities from seizing residents' economic impact payments.
- **June 4:** The House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies <u>convened</u> a hearing to discuss the Centers for Disease Control and Prevention (CDC) response to the COVID-19 pandemic (WHG client <u>summary</u>).
- **June 3**: House Energy and Commerce Committee leaders and Senate Finance Committee leaders sent a bipartisan letter urging HHS to disperse COVID-19 relief fund to Medicaid providers.
- May 28: Sen. Elizabeth Warren (D-MA) and other Democrats sent a letter to the Department of Labor's Office of Inspector General requesting an audit of OSHA's handling of inspections and citations during the COVID-19 pandemic (WHG client summary).
- May 28: The House Education and Labor Subcommittee on Workforce Protections convened a
 hearing to examine the federal government's actions to protect workers from COVID-19 (WHG
 client summary).
- May 26: The House Oversight and Reform Committee <u>convened</u> a briefing with the Department of Health and Human Services (HHS) Principal Deputy Inspector General (IG) Christi Grimm to examine the Administration's COVID-19 response (WHG client <u>summary</u>).
- 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).
- 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>)
- 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>).
- **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.
- 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 <u>summary</u>).

- 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 summary).
- 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 summary).
- 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) sent 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 summary).
- **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 summary).
- 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) <u>sent</u> a <u>letter</u> 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) <u>sent</u> 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</u> CMS 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 summary).
- **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 <u>sent</u> 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,

<u>Washington</u> and <u>Massachusetts</u> 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 legislation)	Funding Amount	Agency	Actionable Dates