

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

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

Updated March 23, 2020

[CMS](#); [FDA](#); [CDC](#); [ASPR](#); [NIH](#); [USDA](#); [IRS](#); [HUD](#); [FEMA](#); [WHITE HOUSE](#); [CONGRESS](#)

CENTERS FOR MEDICARE & MEDICAID SERVICES

Infection Control and Prevention

- **March 17:** CMS issued COVID-19 [guidance](#) to all Programs of All-Inclusive Care for the Elderly (**PACE**) **Organizations** (POs). PACE is a Medicare and Medicaid program that helps people meet their healthcare needs in the community instead of going to a nursing home or other care facility.
- **March 13:** CMS released a [fact sheet](#) ([press release](#)) outlining provider flexibilities in response to the national emergency declaration, including Section 1135 waivers of certain Medicare, Medicaid, and CHIP requirements and how they apply to different settings of care. (WHG client [summary](#)). The transcript and audio recording from a National Stakeholder Call on these flexibilities is available [here](#).
- **March 13:** CMS released an updated [memorandum](#) based on recommendations from the CDC directing **nursing homes** to significantly restrict visitors and nonessential personnel, as well as restrict communal activities inside nursing homes.
- **March 10:** CMS issued memoranda to **dialysis facilities** ([here](#)) and **home health** providers ([here](#)) on screening and containment strategies for patients, visitors, and staff. (WHG client [summary](#)).
- **March 9:** CMS published [guidance](#) to hospitals with **emergency departments** (EDs) on patient screening, treatment and transfer requirements to prevent the spread of infectious disease and illness, including COVID-19.

- **March 9:** CMS released [guidance](#) on the screening, treatment and transfer procedures healthcare workers must follow when interacting with patients to prevent the spread of COVID-19 in a **hospice** setting. CMS also issued [guidance](#) specific to nursing homes to help control and prevent the spread of the virus (WHG client [summary](#)).
- **March 4:** CMS [announced](#) new actions the agency is taking to limit the spread of COVID-19, and released a series of memoranda for U.S. health care facilities and **nursing homes** on how they should respond to and contain the threat of the outbreak. (WHG client [summary](#)).

Personal Protective Equipment (PPE)

- **March 18:** CMS issued tiered [recommendations](#) ([press release](#)) for health care providers on limiting non-essential adult elective surgery and medical and surgical procedures, including all dental procedures. (WHG client [summary](#)).
- **March 10:** CMS issued guidance on the CDC's updated Personal Protective Equipment (PPE) recommendations for health care workers. (WHG client [summary](#)).

Telehealth & Provider Enrollment

- **March 22:** CMS released [FAQs](#) on Medicare Provider Enrollment Relief related to COVID-19 including the toll-free hotlines available to provide expedited enrollment and answer questions related to COVID-19 enrollment requirements.
- **March 20:** CMS released two toolkits – one for general practitioners ([here](#)) and one for providers treating end-stage renal disease ([here](#)) – collating key resources in answering telehealth-related questions. (WHG client [summary](#)).
- **March 17:** CMS released anticipated guidance on new Medicare telehealth flexibilities triggered by the national emergency declaration in response to the COVID-19 outbreak ([press release](#); [accompanying FAQs](#); [accompanying document](#)). Effectuated per authorities granted under the coronavirus emergency supplemental bill. (WHG client [summary](#)).
- **March 9:** CMS issued a [press release](#) highlighting the telehealth benefits in the agency's Medicare program for use by patients and providers.

Coding and Reimbursement

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

Benefits and Coverages

- **March 18:** CMS issued [FAQs](#) to clarify coverage for the diagnosis and treatment of COVID-19 by catastrophic health plans.
- **March 13:** CMS released a [fact sheet](#) to assist Medicare providers with information related to the price of CDC tests and non-CDC tests for COVID-19. (WHG client [summary](#)).

- **March 12:** CMS issued Frequently Asked Questions ([FAQs](#)) to ensure individuals, issuers and states have clear information on coverage benefits for COVID-19 based on the ACA’s essential health benefits (EHBs).
- **March 12:** CMS provided additional information on coronavirus response strategies for Medicaid and CHIP agencies (WHG client [summary](#)).
- **March 10:** CMS issued [guidance](#) to help Medicare Advantage and Part D plans respond to the coronavirus (WHG client [summary](#)).

For States, State Survey Agencies, Accrediting Organizations

- **March 23:** CMS [released](#) a [fact sheet](#) outlining a targeted, streamlined survey process for healthcare facility inspections, further refined from guidance provided earlier this month. The agency issued the guidance based in part on findings of a recent inspection of the Life Care Center **nursing home** in Kirkland, Washington – the epicenter of the COVID-19 outbreak in that state.
- **March 23:** CMS [announced](#) the approval of 1135 waiver requests from 11 states, including: [Alabama](#), [Arizona](#), [California](#), [Illinois](#), [Louisiana](#), [Mississippi](#), [New Hampshire](#), [New Jersey](#), [New Mexico](#), [North Carolina](#), and [Virginia](#). Additional Section 1135 approval letters will be posted [here](#) as they are issued. (WHG client [summary](#)).
- **March 22:** CMS released new checklists and tools designed to support state Medicaid and CHIP programs in pursuing the various regulatory flexibilities that became available when President Trump declared COVID-19 a national emergency. (WHG client [summary](#)).
- **March 19:** CMS [approved](#) an 1135 Medicaid waiver request for the state of Washington.
- **March 17:** CMS [approved](#) a Section 1135 waiver request for the state of Florida in response to the COVID-19 national emergency, which will allow the state to waive prior authorization requirements, streamline provider enrollment processes, allow care to be provided in alternative settings, and more. Additional Section 1135 approval letters will be posted [here](#) as they are issued.
- **March 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](#)).

FOOD & DRUG ADMINISTRATION

Remote Patient Monitoring

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

Treatments and Vaccines

- **March 18:** FDA [issued](#) guidance on conducting clinical trials during the COVID-19 outbreak, including considerations for protocol modifications (WHG client [summary](#)).
- **March 9:** FDA and FTC [warned](#) seven companies selling products claiming to treat or prevent COVID-19. FDA notes these products are unapproved and pose a significant risk to patient health.

Personal Protective Equipment (PPE)

- **March 22:** FDA [issued](#) guidance to expand the manufacturing and availability of ventilators and other respiratory devices, such as CPAP machines (WHG client [summary](#)).
- **March 20:** FDA [issued](#) two temporary policies to increase the production of alcohol-based hand sanitizer. Under the guidance manufacturing firms, pharmacies, and outsourcing facilities may produce or compound handrub products (WHG client [summary](#)).
- **March 11:** FDA [issued](#) a letter to health care providers on recommendations for mask and gown conservation (WHG client [summary](#)).
- **March 2:** FDA and CDC [took action](#) to allow certain National Institute for Occupational Safety and Health (NIOSH) approved respirators not currently regulated by the FDA to be used in the health care setting by health care personnel.

Diagnostic Testing

- **March 21:** FDA [issued](#) the first emergency use authorization (EUA) for a point-of-care COVID-19 diagnostic for the Cepheid Xpert Xpress SARS-CoV-2 test.
- **March 20:** FDA [warns](#) consumers about unauthorized fraudulent COVID-19 test kits.
- **March 16:** FDA [announced](#) new state flexibility to authorize diagnostic test and updated existing policy to include commercial manufacturers (WHG client [summary](#)).
- **March 16:** FDA [issued](#) two additional Emergency Use Authorization (EUA) diagnostics to Hologic for its Panther Fusion SARS-COV-2 Assay and to Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.
- **March 13:** FDA [issued](#) the fourth COVID-19 Emergency Use Authorization (EUA) diagnostic to Thermo Fisher for its TaqPath COVID-19 Combo kit.
- **March 12:** FDA [issued](#) new flexibilities to the New York State Department of Health to address the COVID-19 outbreak and issued the third Emergency Use Authorization diagnostic. (WHG client [summary](#)).
- **February 29:** FDA [issued](#) Emergency Use Authorizations (EUAs) to two public health labs in New York for diagnostics to test COVID-19.

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

Food Safety

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

CENTERS FOR DISEASE CONTROL & PREVENTION

Treatment

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

For Providers

- **March 18:** CDC released [Prepare to Care for COVID-19](#) - a new resource containing clinical tools for health care providers caring for patients with COVID-19. The resource includes steps clinicians can take to prepare their clinic to protect patients and health care workers from COVID-19 (before patients arrive, when patients arrive, and after patients are assessed); outdoor and indoor signs; and a patient handout with tips for home care.
- **March 18:** CDC released a [Morbidity and Mortality Weekly Report \(MMWR\)](#) titled, "Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) - United States, February 12-March 16, 2020.
- **March 17:** CDC updated its [FAQs for healthcare professionals](#) on COVID-19 regarding whether pregnant health care personnel are at increased risk if they care for patients with COVID-19. CDC recommends pregnant healthcare personnel to follow risk assessment and infection control guidelines for personnel exposed to patients with suspected or confirmed COVID-19.
- **March 11:** HHS [Announced](#) that the CDC is moving forward with awarding more than \$560 million of the \$8.3 billion in supplemental spending passed by Congress. The funding will be provided to states, localities, territories, and tribes, to assist with the coronavirus response.

For the Public

- **March 23:** CDC [will provide](#) \$80 million in funding to tribes, tribal organizations, and Urban Indian Organizations for resources to support the 2019 novel coronavirus (COVID-19) response. (WHG client [summary](#)).
- **March 11:** CDC [Released](#) mitigation strategies to help stop the spread of the coronavirus (WHG client [summary](#)).

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

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

- **March 21:** BARDA [announced](#) will provide support for a U.S. [Phase 2/3 clinical](#) trial to evaluate Kevzara – developed under a collaboration between Regeneron and Sanofi for the treatment of rheumatoid arthritis – as a potential treatment for severely ill COVID-19 patients.
- **March 18:** ASPR [announced](#) a public-private partnership to create a high-speed, high-volume, emergency drug packaging solution using low-cost prefilled syringes (WHG client [summary](#)).
- **March 18:** BARDA [announced](#) it would help fund development of a fourth COVID-19 diagnostic test (WHG client [summary](#)).
- **March 13:** The Biomedical Advanced Research and Development Authority (BARDA) within ASPR [provided](#) advanced support to rapidly develop two diagnostic tests for COVID-19, Simplexa COVID-19 Direct Assay and QIAstat-Dx RPS2 test.
- **March 9:** ASPR [announced](#) it will provide advanced development support to a diagnostic test for COVID-19 that can be used to process up to 1,000 tests in 24 hours, which is being developed by Hologic, Inc. (WHG client [summary](#)).
- **March 4:** ASPR [announced](#) its intent to purchase 500 million N95 respirators over the next 18 months for the Strategic National Stockpile.
- **February 18:** ASPR announced collaboration with [Janssen](#) and [Sanofi](#) for the development of COVID-19 therapeutics and vaccines, respectively.

NATIONAL INSTITUTES OF HEALTH

- **March 17:** NIH, expressing concern for the health and safety of people involved in NIH research, issued [guidance](#) and information on flexibilities for NIH applicants and grantees.
- **March 16:** NIH [announced](#) the beginning of the first Phase I clinical trial for an investigational COVID-19 vaccine. The Seattle-based trial will enroll 45 healthy adult volunteers and will last approximately six weeks (WHG client [summary](#)).
- **Feb. 25:** NIH [announced](#) the beginning of a randomized, controlled clinical trial to evaluate the safety and efficacy of the investigational antiviral remdesivir in hospitalized adults diagnosed with COVID-19 at the University of Nebraska Medical Center (UNMC) in Omaha.

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

- **March 17:** USDA Secretary Perdue [announced a collaboration](#) with the Baylor Collaborative on Hunger and Poverty, McLane Global, PepsiCo, and others to deliver nearly 1,000,000 meals per

week to students in a limited number of rural schools closed due to COVID-19. Eligibility details for schools is [here](#).

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

THE INTERNAL REVENUE SERVICE

- **March 18:** The IRS [announced](#) that it is automatically extending federal income tax payment deadlines for individuals (up to \$1 million of 2019 tax due) and corporations (up to \$10 million of 2019 tax due) to July 15, 2020. Formal guidance is available [here](#).
- **March 11:** The IRS [announced](#) that high deductible health plans (HDHPs) are able to cover coronavirus costs without cost-sharing.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

- **March 18:** HUD Secretary Ben Carson, in consultation with the Trump Administration and the Coronavirus Task Force, authorized the Federal Housing Administration (FHA) to implement an immediate [foreclosure and eviction moratorium](#) ([press release](#)) for single family homeowners with FHA-insured mortgages for the next 60 days.

FEDERAL EMERGENCY MANAGEMENT AGENCY

- **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](#)).

THE WHITE HOUSE

- **March 22:** President Trump issued a [memorandum](#) outlining federal support measures for states using the National Guard in response to the COVID-19 outbreak. (WHG client [summary](#)).
- **March 18:** President Trump signed the Families First Coronavirus Response Act ([H.R. 6201](#)) into law.
- **March 18:** President Trump delivered [remarks](#) indicating that the Administration will be invoking the Defense Production Act, “just in case,” and deploying two military hospital ships – one to New York and one to California – among other actions. This was followed by an [Executive Order](#) on Prioritizing and Allocating Health and Medical Resources.
- **March 16:** President Trump and the White House Coronavirus Task Force issued new [guidelines](#) to help protect Americans during the global Coronavirus outbreak, called 15 Days to Slow the Spread.

- **March 13:** President Trump officially [classified](#) the COVID-19 outbreak as a national emergency, under the Stafford Act.
- **March 11:** President Trump [announced](#) a travel ban to Europe during a primetime news briefing to the nation.
- **March 6:** President Trump signed into law [H.R. 6074](#), the \$8.3 billion emergency supplemental appropriation to address the coronavirus (COVID-19) outbreak. (WHG client [summary](#)).
- **March 3:** President Trump issued a proclamation restricting travel into the United States from non-citizens who were present in Iran during the 14-day preceding their attempted entry into the United States. (WHG client [summary](#)).
- **March 2:** White House and agency leaders spoke with the business community about COVID-19, how the government is responding, and what businesses are urged to do to limit exposure and spread. (WHG client [summary](#)).

CONGRESSIONAL RESPONSE

Legislation

- **March 23:** House Democrats [introduced](#) the Take Responsibility for Workers and Families Act – a package of proposals intended to bolster the federal government’s response to COVID-19, as well as provide economic relief to individuals and businesses (including hospitals).
- **March 22:** On Sunday evening, March 22, 2020, the Senate [rejected](#) (47-47) a motion to proceed to Senate Majority Leader McConnell’s updated \$1.6 trillion COVID-19 economic stimulus package – the CARES Act. The bill text had been updated to include various Medicare, Medicaid and other key health care “extenders” and appropriations language; however, Democrats objected to its so-called “no-strings attached corporate slush fund” and inadequate funding for hospitals and individuals. (WHG client [summary](#)).
- **March 19:** Senate Majority Leader Mitch McConnell (R-KY) released the Coronavirus Aid, Relief, and Economic Security (CARES) Act – the “phase 3” coronavirus stimulus package. (WHG client [summary](#)).
- **March 18:** President Trump signed the Families First Coronavirus Response Act ([H.R. 6201](#)) into law.
- **March 18:** The Senate passed the Families First Coronavirus Response Act ([H.R. 6201](#)) by a vote of 90-8.
- **March 16:** The House approved by unanimous consent H.Res. 904 to make technical corrections to the Families First Coronavirus Response Act (H.R. 6201). (WHG client [summary](#)).
- **March 14:** The House [passed](#) the Families First Coronavirus Response Act ([H.R. 6201](#)) by a vote of 363-40 ([details](#)). Relating to health care, the approved version contained several changes –

most notably, the House approved a Medicaid Federal medical assistant percentage (FMAP) of 6.2 percent instead of the initially proposed 8 percent.

- **March 12:** Sen. Tina Smith (D-MN) [led](#) a group of Democratic Senate colleagues in introducing the Free COVID-19 Testing Act ([Details](#)).
- **March 11:** House Democrats [introduced](#) the Families First Coronavirus Response Act ([H.R. 6201](#)) – a package of bills intended to bolster the federal government’s response to the coronavirus outbreak and address the safety and financial impacts in communities (WHG client [summary](#)).
- **March 10:** House Education and Labor Committee Chairman Bobby Scott (D-VA), Rep. Donna Shalala (D-FL), and Committee Democrats introduced the COVID-19 Worker Protection Act of 2020 ([H.R. 6139](#)). The bill was incorporated into introduced version of H.R. 6201, but was not included in the final version approved by the House. (WHG client [summary](#)).
- **March 6:** The President signed the \$8.3 billion emergency supplemental appropriation bill to address the COVID-19 outbreak into law. (WHG client [summary](#)).
- **March 5:** The Senate [voted](#) 91-1 to pass [H.R. 6074](#), the House-passed \$8.3 billion emergency supplemental appropriation to address the coronavirus (COVID-19) outbreak. The sole “no” vote was from Senator Rand Paul (R-KY). (WHG client [summary](#)).

Oversight and Other

- **March 19:** Sen. Chris Murphy (D-CT) [led](#) 16 Senate Democrats in a letter urging seven private health insurers to fully cover testing and treatment for COVID-19 and associated health complications with no cost-sharing. (WHG client [summary](#)).
- **March 17:** House E&C Committee Chairman Frank Pallone, Jr. (D-NJ) and other Democratic committee leaders [sent](#) a letter, urging the Federal Trade Commission (FTC) to take immediate action to protect consumers from price gouging during the COVID-19 public health emergency.
- **March 16:** Senate Democrats released their “[Economic and Community Services Proposal](#),” which includes proposals to address lost wages, paid sick days and loan payment relief; small business and local economic relief; and housing, food security, and education.
- **March 13:** More than 100 House Democrats [sent](#) a letter, urging HHS Secretary Alex Azar to establish a Special Enrollment Period (SEP) for qualified individuals to obtain coverage through the federal exchange or state-based exchanges during the COVID-19 pandemic. Of note, [Washington](#) and [Massachusetts](#) have announced that they will offer a SEP due to the pandemic through April 8 and 25, respectively.
- **March 13:** The Congressional Research Service (CRS) released a [brief report](#) discussing the potential challenges of COVID-19 to the United States’ blood supply. (WHG client [summary](#)).
- **March 9:** The Congressional Research Service (CRS) released a [summary](#) of FAQs regarding the development and regulation of domestic diagnostic testing for COVID-19.

- **March 6:** Senate Special Committee on Aging Chairwoman Susan Collins (R-ME) and Ranking Member Bob Casey (D-PA) led a bipartisan letter to HHS Secretary Alex Azar, urging the Department to “consider the unique health needs of older Americans in all aspects of the domestic response.” (WHG client [summary](#)).
- **March 4:** House Ways and Means Committee Chairman Richard Neal (D-MA) and Rep. Suzan DelBene (D-WA) [sent](#) a [letter](#) to the CMS Administrator Seema Verma, requesting information on how the agency is assisting skilled nursing facilities (SNFs) and nursing facilities (NFs) to prevent the spread of coronavirus (COVID-19). The information is due by March 6, 2020. (WHG client [summary](#)).