

HHS COVID-19 April 21, 2020 Update

Provider Relief Fund Update: The CARES Act appropriated \$100 billion to establish a Provider Relief Fund. This fund, administered by the Secretary of HHS, is being used to distribute payments to health care entities across the country that have been affected by the coronavirus. To date, \$30 billion has been distributed generally to health care entities across the country.

HHS will soon make targeted distributions to hospitals and other facilities that have been particularly affected by the increased burden of caring for those with the coronavirus. To inform how these funds are distributed, HHS is asking all hospitals to provide the following information:

- For each facility with a Medicare Tax Identification Number (TIN):
 - Total number of Intensive Care Unit beds as of April 10, 2020
 - Total number of admissions with a positive diagnosis for COVID-19 from January 1, 2020 to April 10, 2020
 - National Provider Identifier

How will providers share the information being requested and what steps do they need to take to be considered for impact funding?

Submitters are being asked to provide this information through an authentication portal established by an HHS vendor, TeleTracking. They will be able to submit this data via data entry at an individual hospital level, entering multiple hospitals at one time, or batch upload of data of multiple hospitals via a designated individual or third-party entity.

The health care provider's site administrator received an email from HHS on Sunday April 12th, or thereafter, with instructions and a link to register on this portal. If providers have not already done so, they should register on the portal as directed in the email.

This process has been created to minimize burden, and should not require more than 10 minutes. If it is not clear who within an organization received this notification, or if providers have questions about the registration process, they can contact TeleTracking Technical Support at 877-570-6903.

To help HHS continue to move provider relief funding out to providers quickly, **submitters must deliver this information by 11:59 p.m. PT, Thursday April 23.** Providers should understand that **submitting the data is a prerequisite to payment,** but is **not a guarantee of eligibility** for any amount.

Testing and Treatment

At-Home Test: The U.S. Food and Drug Administration authorized the first diagnostic test with a home collection option for COVID-19. Specifically, the FDA re-issued the [emergency use authorization \(EUA\) for the Laboratory Corporation of America \(LabCorp\) COVID-19 RT-PCR Test](#) to permit testing of samples self-collected by patients at home using LabCorp's Pixel by LabCorp COVID-19 Test home collection kit. This reissued EUA for LabCorp's molecular test permits testing of a sample collected from the patient's nose using a designated self-collection kit that contains nasal swabs and saline. Once patients self-swab to collect their nasal sample, they mail their sample, in an insulated package, to a LabCorp lab for testing.

Rapid Diagnostic Test: BARDA entered into a [partnership with Tangen Biosciences](#) to develop a rapid diagnostic test using technology that might help health departments monitor the pandemic more efficiently in their community and results are provided to users and integrated through a cloud-based mobile platform that could convey the identified test results to public health agencies. This could help public health departments assess the spread in the community and decrease the number of infections.

Compounding Drugs with Shortages: FDA has released a temporary policy for [compounding of certain drugs](#) for hospitalized patients by pharmacy compounders not registered as outsourcing facilities guidance for industry. Many hospitals are currently experiencing difficulties accessing FDA-approved drug products used for patients with COVID-19. As a temporary measure during the public health emergency related to COVID-19, or for such shorter time as FDA may announce by updating or withdrawing this guidance based on evolving needs and circumstances, FDA does not intend to take action against a pharmacy for compounding a drug that is essentially a copy of a commercially available drug, or for providing a drug to a hospital without obtaining a patient-specific prescription.

Reporting Clinical Trial Data: CMS is encouraging clinicians who participate in the Quality Payment Program (QPP), such as physicians, physician assistants, nurse practitioners, and others, to contribute to scientific research and evidence to fight the Coronavirus Disease 2019 (COVID-19) pandemic. [Clinicians may now earn credit in the Merit-based Incentive Payment System \(MIPS\)](#), a performance-based track of QPP that incentivizes quality and value, for participation in a clinical trial and reporting clinical information by attesting to the new *COVID-19 Clinical Trials* improvement activity. This action will provide vital data to help drive improvement in patient care and develop innovative best practices to manage the spread of COVID-19 within communities.

Treatment Guidelines: NIH developed [Treatment Guidelines](#) to inform clinicians how to care for patients with COVID-19. The recommendations in these Guidelines are based on scientific evidence and expert opinion. Each recommendation includes two ratings: a letter (A, B, or C) that indicates the strength of the recommendation and a Roman numeral (I, II, or III) that indicates the quality of the evidence that supports the recommendation.

Treatment Acceleration Program: FDA launched the [Coronavirus Treatment Acceleration Program \(CTAP\)](#) to speed approval of drugs and therapies. To date, 72 therapies are now being tested and another 211 are in active planning for clinical trials. Commissioner Hahn [posted a blog](#) about the program and notes that the program uses every available method to move new treatments to patients as quickly as possible, while at the same time finding out whether the treatments are helpful or harmful.

Diagnostics Update to Date: During the COVID-19 pandemic, the FDA has worked with more than 340 test developers who have said they will be submitting emergency use authorization (EUA) requests to FDA for tests that detect the virus. To date, the FDA has issued 41 individual [emergency use authorizations](#) for test kit manufacturers and laboratories. In addition, 16 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs). The FDA has been notified that more than 210 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its [COVID-19 Diagnostics FAQ](#) up to date.

PPE and Supplies

Expanding Ventilator Capacity: On April 20, President Trump launched the Dynamic Ventilator Reserve Program, an innovative public-private partnership to access up to 65,000 additional ventilators in hospitals across the country that can be redeployed when not in use.

Update on Face Masks: The FDA issued a [face mask emergency use authorization \(EUA\)](#) in response to concerns relating to insufficient supply and availability of face masks for use by members of the general public, including health care personnel in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the SARS-CoV-2 virus during the pandemic. Manufacturers of face masks that are used as described in the EUA and meet the requirements in the EUA, do not need to take any action, other than complying with the Conditions of Authorization in the EUA, to be authorized under this EUA.

Funding, Resources and Toolkits

Nearly \$1 Billion in COVID-19 Services and Supports for Older Adults and People with Disabilities: HHS announced [nearly \\$1 Billion in CARES Act](#) funding to states, Tribes and community-based organizations to help meet the needs of older adults and people with disabilities as communities implement measures to prevent the spread of COVID-19. The grants will fund home-delivered meals; care services in the home; respite care and other support to families and caregivers; information about and referral to supports; and more. The majority of these additional funds (\$905 million) are being awarded today to states, territories, and tribes for subsequent allocation to local service providers. Grant amounts are determined based on the formulas defined under the program authorizing statutes.

Funding for Tribes: Through the CARES Act, HRSA received [\\$15M to allocate to tribes, tribal organizations, urban Indian health organizations, and health service providers to tribes](#). The funding will provide support for the Tribes to prevent, prepare, and respond to COVID-19 in rural communities. The Notice of Funding Opportunity can be found [here](#) and applications are due May 6, 2020.

Resources for Human Services Leaders: [The Administration on Children and Families created a resource](#) that is geared towards state leaders and is intended to provide current mandatory program flexibilities, guidance and resources in ACF programs, as well as information on other federal programs that serve vulnerable children and families. Information will be updated periodically.

Toolkit on Healthcare Workforce: The Technical Resource Assistance Center posted the COVID-19 [workforce virtual toolkits](#). This toolkit includes resources and tools for decision-makers managing healthcare workforce challenges in response to COVID-19 emergency. Additionally, information on federal regulatory and funding flexibility, healthcare workforce training, liability protection, scope of practice, and workforce protection is also included on the site.

Toolkit on Alternative Care Sites: HHS released this [Toolkit and guidance](#) to help state, local, tribal, and territorial (SLTT) entities address potential capacity and capability gaps in healthcare systems during the 2020 SARS-CoV2 virus (COVID-19) pandemic. It is intended to provide guidance and technical assistance to SLTT entities in establishing and operationalizing Alternate Care Sites (ACS) used to care for COVID-19-positive or presumed positive patients. If an ACS is used to treat non-COVID-19 patients, additional considerations will apply.

Waivers and Flexibilities:

CMS Waiver Flexibility: CMS has [approved 53 COVID-related emergency waivers](#), 39 state amendments, 16 COVID-related Medicaid Disaster Amendments and one CHIP COVID-related Disaster Amendment. States are using a toolkit CMS developed to expedite the application and approval of Medicaid state waivers and State Plan Amendments.

Rural Health Clinic and Federally-Qualified Health Center Flexibilities: CMS released information for [RHCs and FQHCs on Telehealth and Virtual Communications Flexibilities](#) During COVID-19. To support RHCs and FQHCs and their patients, Congress and CMS made changes to requirements and payments during the COVID-19 Public Health Emergency, including: New payment for telehealth services, including how to bill Medicare; Expansion of virtual communication services; Revision of home health agency shortage requirement for visiting nursing services; Consent for care management and virtual communication services; and Accelerated/advance payments.

Extension on the Interoperability and Patient Access Final Rule: Today, the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare & Medicaid Services

(CMS), in conjunction with the HHS Office of Inspector General (OIG) announced a [policy of enforcement discretion](#) to allow compliance flexibilities regarding the implementation of the interoperability final rules announced on March 9th in response to the coronavirus disease (COVID-19) public health emergency. ONC will exercise enforcement discretion for 3 months at the end of certain ONC Health IT Certification Program compliance dates associated with the ONC Cures Act Final Rule. CMS will provide hospitals an additional 6 months to implement the new requirements.

Information for Specific Populations

Extension of an Order to Suspend Certain Individuals into the US: CDC announced an [extension of an Order](#) issued March 20, 2020 under Sections 362 and 365 of the Public Health Service Act, and associated implementing regulations, that suspends the introduction of certain persons from countries where an outbreak of a communicable disease exists. The Order shall continue in operation for an additional 30 days.

Guidance for Childcare Programs: CDC updated their [guidance for childcare programs](#) that remain open. The updates include additional options for screening children upon arrival to ensure that children who have a fever or other signs of illness are not admitted to the facility and noting that the additional options may be useful when personal protective equipment (PPE) is in short supply.

Safety Practices for Workers Exposed to a Person with COVID-19: CDC updated their guidance on [implementing safety practices for critical infrastructure workers who may have had exposure to a person with suspected or confirmed COVID-19](#). To ensure continuity of operations of essential functions, CDC advises that critical infrastructure workers may be permitted to continue work following potential exposure to COVID-19, provided they remain asymptomatic and additional precautions are implemented to protect them and the community. Critical Infrastructure workers who have had an exposure but remain asymptomatic should adhere to outlined practices prior to and during their work shift.

Aligning Federal Agency Operations with Opening Up America Guidelines: The White House released a document on [aligning federal agency operations with the national guidelines for opening up America again](#). In partnership with state, local, tribal, and territorial governments, and the private sector, the Federal government is actively planning to ramp back up government operations to the maximum extent possible, as local conditions warrant, consistent with the National guidelines for Opening Up America Again.

Information for Laboratories: CDC updated their [information for laboratories](#). This page includes interim guidance and resources for laboratory professionals working with specimens from persons under investigation (PUI) for coronavirus disease 2019 (COVID-19).

Information for Institutes of Higher Education: CDC updated their [guidance for institutes of higher education](#). The updates now include a decision-tree for school closures.

Updated Information for Homeless Shelters: CDC released additional information on [screening clients at homeless shelters](#). The following is a screening tool that can be used to identify people with symptoms that indicate they might have a respiratory infection. Although not every person who has respiratory infection symptoms will have coronavirus disease 2019 (COVID-19), using a tool may be helpful in identifying people who may need medical care.

Report on Effect of Cleaning and Disinfectant Chemicals and COVID-19: CDC published a report, [Cleaning and Disinfectant Chemical Exposures and Temporal Associations with COVID-19 — National Poison Data System, United States, January 1, 2020–March 31, 2020](#). This report describes a temporal association between COVID-19 cleaning recommendations—from public health agencies and the media—and an increase in reports related to cleaners and disinfectants reported to the National Poison Data System (NPDS).