

**Department of Health and Human Services**

**Spend Plan to Pandemic Response Accountability Committee**

June 25, 2020

## OVERVIEW

The purpose of this document is to satisfy the spend plan requirement contained in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116-136, Section 15011(b)(1)(B). The information contained herein reflects the Department of Health and Human Services' current spend plans for the use of Coronavirus supplemental appropriations, including resources to support covered entities.

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**Department of Health and Human Services**

**Coronavirus Preparedness and Response Supplemental  
Appropriations Act, 2020 Spend Plan – UPDATE**

**1<sup>st</sup> 60-day Update to Congress**

/JEN MOUGHALIAN/

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## INTRODUCTION

The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123) provided \$6.497 billion in emergency supplemental funding to the Department of Health and Human Services (HHS) for Coronavirus preparedness and response activities. The Act allocated \$2.2 billion to the Centers for Disease Control and Prevention (CDC), \$61 million to the Food and Drug Administration (FDA), \$836 million to the National Institutes of Health (NIH), and \$3.4 billion to the Public Health and Social Services Emergency Fund (PHSSEF) including \$300 million only available upon certification to the Appropriations Committees that additional funds are necessary to purchase vaccines, therapeutics, or diagnostics. This report provides the first 60-day update submitted to the Committees as requested in the Section 305 reporting requirements below. This report includes any updates to the summary table providing Department-wide totals.

The reporting requirements within Section 305 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123) states:

Sec. 305. – Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall provide a detailed spend plan of anticipated uses of funds made available to the Department of Health and Human Services in this Act, including estimated personnel and administrative costs, to the Committees on Appropriations of the House of Representatives and the Senate: *Provided*, That such plans shall be updated and submitted to such Committees every 60 days until September 30, 2024: *Provided further*, That the spend plans shall be accompanied by a listing of each contract obligation incurred that exceeds \$5,000,000 which has not previously been reported, including the amount of each such obligation.

The following spend plan details the planned uses of the supplemental funds appropriated to HHS. With these resources, HHS will further enhance domestic and international preparedness and response for COVID-19; contain and mitigate the spread of COVID-19 in the United States; accelerate the development, testing, and availability of vaccines, therapeutics, diagnostics, and necessary medical supplies; and make critical investments in public health capacity to ensure State, local, and Federal entities are able to prepare for, prevent, and respond to COVID-19 and related health conditions. The USG strategy may evolve over time to respond to the changing factors of the COVID-19 outbreak.

**Coronavirus Preparedness and Response Supplemental  
Appropriations Act, 2020 Spend Plan – UPDATE  
(As of June 4<sup>th</sup>, 2020)**

As of June 4<sup>th</sup>, 2020, the Department of Health and Human Services (HHS) is reporting updates to activities reported in the original spend plan of the \$6.497 billion appropriated in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116 123). Updated activity descriptions and planned uses of funds have been included for the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and the Office of the Assistant Secretary for Preparedness and Response (ASPR).

To respond to the growing global presence of COVID-19, the United States has supported a government-wide response to combat the virus and limit the negative health outcomes which can result. HHS has and continues to work with partners across the Federal government, states, and the private sector. Activities include aiding domestic and international public health preparedness and response efforts; conducting public health surveillance, epidemiology, and laboratory testing; quarantining individuals who pose a risk of transmitting the virus; training health care workers; advancing the development, testing, and availability of new vaccines, therapeutics, and diagnostics; advancing manufacturing enhancements; and procuring and deploying necessary medical supplies following required notification. Supplemental funding appropriated to HHS will support activities across the Department to enhance ongoing efforts and continue a comprehensive and coordinated response to contain and mitigate COVID-19.

**HHS Coronavirus Supplemental Funding Spend Plan**  
*(dollars in millions)*

<b>Budget Activity</b>	<b>HHS Supplemental Funding</b>
<b><u>Centers for Disease Control and Prevention</u></b>	<b>2,200.0</b>
<i>Domestic Cooperative Agreements</i>	952.0
<i>Public Health Response</i>	648.0
<i>Global Disease Detection and Emergency Response</i>	300.0
<i>Infectious Diseases Rapid Response Reserve Fund</i>	300.0
<b><u>National Institutes of Health</u></b>	<b>836.0</b>
<i>National Institute of Allergy and Infectious Diseases</i>	826.0
<i>National Institute of Environmental Health Sciences</i>	10.0
<b><u>Public Health and Social Services Emergency Fund</u></b>	<b>3,400.0</b>
<i>Assistant Secretary for Preparedness and Response</i>	2,798.0
<i>Health Resources and Service Administration – Health Centers</i>	100.0
<i>Additional Contingency Funds for Product Purchases</i>	300.0
<i>Other Preparedness and Response Activities</i>	200.0

<i>Office of Inspector General</i>	<i>2.0</i>
<b><u>Food and Drug Administration</u></b>	<b>61.0</b>
<i>Salaries and Expenses</i>	<i>61.0</i>
<b>Total, HHS Coronavirus Supplemental Funding</b>	<b>6,497.0</b>

# CENTERS FOR DISEASE CONTROL AND PREVENTION

## Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020

(Dollars in millions)

<b>Activity</b>	<b>Amount</b>
COVID-19 Response and Preparedness <sup>1</sup>	
<i>Domestic Cooperative Agreements</i>	952.000
<i>Public Health Response</i>	648.000
<i>Global Disease Detection and Emergency Response</i>	300.000
<i>Infectious Diseases Rapid Response Reserve Fund (IDRRRF)</i> <sup>2</sup>	300.000
<b>Total, CDC Coronavirus Funding</b>	<b>2,200.000</b>

<sup>1</sup>Funds will be returned from the Secretary's transfer, as appropriate.

<sup>2</sup>Deposit into the IDRRRF; CDC has no plans to use these funds at this time.

Over 896,000 global cases of 2019 Novel Coronavirus (COVID-19) have been confirmed, with more than 45,000 deaths. Cases of COVID-19 infection have now been detected in more than 200 countries or jurisdictions worldwide, and an increased number of countries are experiencing community transmission of the virus. As of April 3, 2020, more than 244,000 cases have been reported in the United States. At this time, the likely trajectory of the viral outbreak, absent further interventions, is unclear. There is much more to learn about the transmissibility, severity, and other features associated with COVID-19; investigations are ongoing. The continued expansion of critical public health activities – including epidemiology, surveillance, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities – are essential to meet the needs in this quickly evolving response. In addition to support for state, local, tribal, and territorial jurisdictions, this funding will also support CDC operations, including deployment of field staff and surge support. As the situation continues to evolve, CDC will update the spend plan as necessary.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Preparedness and Response Supplemental Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$2.2 billion included for CDC in the Coronavirus Preparedness and Response Supplemental Act, 2020.

### **Planned Activities**

#### Domestic Cooperative Agreements (\$952 million)

Through grants to state, local, tribal and territorial jurisdictions, CDC will support core public health response activities, including epidemiology, surveillance, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities:

- Using the Cooperative Agreement for Emergency Response: Public Health Crisis Response, CDC awarded close to \$750 million to 65 recipients (states, tribes, locals, and territories). Funds from this initial award were available for a variety of immediate response activities.

- Using the existing Epidemiology and Laboratory Capacity (ELC) cooperative agreement, CDC awarded \$10 million to state and local jurisdictions to begin implementation of coronavirus surveillance across the U.S., building on existing influenza activities and other surveillance systems. At the end of May, CDC used the ELC again to award \$80 million to 64 recipients for infection prevention and control training of the healthcare workforce.
- Using the existing Emerging Infections Program (EIP) cooperative agreement, CDC awarded more than \$26 million to 10 recipients to enhance surveillance capabilities, including investigating and assessing the burden and severity of COVID-19, evaluating and determining risk factors and outcomes, and assessing exposed/infected healthcare personnel to better identify risk factors for COVID-19 infection. CDC announced \$80 million to support tribal nations, tribal organizations, urban Indian health organizations, or health services providers to tribal entities, significantly above the direction from Congress to allocate a minimum of \$40 million:
  - \$30 million was awarded through a supplement to an existing cooperative agreement to directly fund the three largest tribal nation recipients and nine regionally designated tribal organizations \$10 million was awarded through a supplement to the national tribal organization recipients under an existing cooperative agreement:
    - \$8 million to the National Council of Urban Indian Health with sub-awards to focus on the 41 urban Indian health centers
    - \$2 million to the National Indian Health Board to conduct national communication activities
  - \$40 million will be awarded for a new non-competitive notice of funding opportunity (NOFO) to reach all Title I and Title V tribal nations eligible to apply for a Federal grant.
- Award by jurisdiction information can be found here: <https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/funding-update.pdf>

Note: Working Capital Fund and program support costs will be supported through the sections below.

#### Public Health Response (\$648 million)

Through contracts, grants, and other technical and advisory support (e.g., through salary and benefits, travel, equipment, supplies, communications, etc.), CDC will:

- Increase its technical assistance for nationwide efforts for epidemiology and surveillance, laboratory capacity, and infection control. This includes technical assistance for state and local efforts around outbreak investigations, laboratory diagnostics, contact tracing and case investigation in jurisdictions to rapidly respond to COVID-19 cases and strengthening reporting capabilities and availability of real-time data and specimens.
- Accelerate the implementation of effective infection control measures across the continuum of care, including safely identifying and isolating suspect patients with COVID-19.
- Continue to develop and disseminate critical guidance, including specific guidance for higher risk populations.



- Continue to develop tools and strategies, provide technical assistance and program support, as well as ensure ongoing communication and coordination among federal, state, local, tribal, and territorial public health agencies and partners throughout the response.
- Support operations, including building laboratory capacity (e.g., supplies and equipment) and the deployment of CDC emergency response field staff to address response needs, and surge staffing capacity to support CDC's emergency response.
- Increase health communications for dissemination of up-to-date information in multiple languages to reach the public and targeted audiences with messaging for all aspects of the response.
- Continue to develop and implement a robust response to the public health risk related to travelers going to and coming from affected countries, including staffing quarantine stations.
- Increase expertise, guidance, and training to reduce the likelihood of spread of COVID-19 across the U.S. and to other countries – including ensuring isolation and quarantine measures are carried out, as needed. CDC will also support state and local capacity to assure compliance with all necessary active monitoring requirements.

Note: Working Capital Fund and program support costs will be spread across relevant activities.

#### Global Disease Detection and Emergency Response (\$300 million)

The goals of CDC's global response to COVID-19 are to limit human-to-human transmission, minimize the impact of COVID-19 in vulnerable countries with limited preparedness capacity, and reduce specific threats that pose current and future risk to the United States.

CDC's global COVID-19 response works toward these goals by meeting the following objectives:

- Strengthen capacity to prevent, detect, investigate and respond to local COVID-19
- Mitigate COVID-19 transmission in the community, across borders, and in healthcare facilities
- Support governments, nongovernmental organizations, and healthcare facilities to rapidly identify, triage, and diagnose potential cases to improve patient care and minimize disruptions to essential health services
- Address crucial unknowns regarding clinical severity, extent of transmission and infection with support for special investigations and other forms of cooperation between CDC and country partners
- Ensure readiness to implement vaccines and therapeutics when available

CDC's technical support is delivered in coordination with the Department of State, the U.S. Agency for International Development, other U.S. government agencies, and multilateral organizations.

Through contracts, grants, and other technical and advisory support (e.g., through salary and benefits, travel, equipment, supplies, communications, etc.), CDC will:

- Work with Ministries of Health and international organizations to support country and regional efforts to control COVID-19 with emergency response, laboratory, surveillance, and epidemiological support; border health; infection prevention, control, and

preparedness in healthcare facilities; and pandemic and vaccine preparedness planning. CDC will support additional cross-cutting partnerships and capacity building work to prepare vulnerable areas for COVID-19.

- Leverage CDC's global presence and regional platforms to quickly go where the disease is through a network of pre-existing relationships and planning frameworks.
- Work on the ground, side-by-side with public health professionals, to focus on building capacity in the core public health capabilities to detect and control emerging health threats, including coronavirus, before there has been significant international transmission.
- Assisting countries with emergency response and planning; laboratory, surveillance, and epidemiology support; border health; infection prevention, control, and preparedness in healthcare facilities; and pandemic and vaccine preparedness planning.

Note: Working Capital Fund and program support costs will be spread across relevant activities.

Infectious Diseases Rapid Response Reserve Fund (\$300 million)

This funding has been deposited in the IDRRRF. At this time, CDC has no plans to use these funds.

## NATIONAL INSTITUTES OF HEALTH

### Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020

(Dollars in millions)

<b>Activity</b>	<b>Amount</b>
Basic Research, Pathogenesis, Animal Models, Epidemiology	195.000
Diagnostics	29.000
Therapeutics	359.000
Vaccines	243.000
<b>Subtotal, NIAID Coronavirus Funding</b>	<b>826.000</b>
Grant Supplements	9.000
Administrative Support	1.000
<b>Subtotal, NIEHS Coronavirus Funding</b>	<b>10.000</b>
<b>Total, NIH Coronavirus Funding</b>	<b>836.000</b>

#### National Institute for Allergy and Infectious Diseases

NIAID will respond to the COVID-19 outbreak by expanding research efforts to accelerate the development of interventions that could help control current and future outbreaks of COVID-19 as well as other coronaviruses with pandemic potential. These activities build on prior NIAID research addressing other coronaviruses, such as those that cause SARS and MERS.

NIAID will expand its research portfolio through grants, contracts and intramural research to focus activities on COVID-19 including an understanding of its pathogenesis, epidemiology and viral biology. Foundational research will include the development of animal models and reagents which are critical to moving forward with the development of countermeasures. NIAID will also support intramural and extramural investigators for the discovery and development of vaccines, therapeutics and diagnostics. Research on vaccines and therapeutics will include costs for pilot lot manufacture, preclinical evaluation, Phase 1 clinical trials and Phase 2/2b clinical trials.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Preparedness and Response Supplemental Act are complementary across programs, take into account evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$826 million included for NIH in the Coronavirus Preparedness and Response Supplemental Act, 2020.

#### **Administrative Costs:**

NIAID's existing administrative infrastructure can efficiently and effectively manage large supplemental funding packages as. Administrative costs will be spread across relevant activities and are estimated to be in the \$8-\$16 million range.

## **Planned Activities – NIAID**

### **Basic Research, Pathogenesis, Animal Models, Epidemiology** (\$195 million)

Investigation of viral natural history, pathogenicity, epidemiology, transmission, and projects to analyze genome sequences and understand viral structures. Mechanism to support these activities will include the following:

- \$82 million will support investigator-initiated grant awards
- \$30 million to support Intramural investigators in Bethesda, Ft. Detrick and Rocky Mountain Labs (RML) in Hamilton, MT
- \$32 million to support R&D contracts
- \$51 million to support solicited grant announcements

### **Diagnostics** (\$29 million)

Development of diagnostic tests for COVID-19 and other Coronaviruses including assays to facilitate preclinical studies. Support will be provided mainly through extramural grants and contracts.

### **Therapeutics** (\$359 million)

Discovery and development of therapeutic candidates for COVID-19 and other coronaviruses including examination of COVID-19 antiviral activity of existing or candidate therapeutics initially developed for other indications, and broad-spectrum therapeutics against multiple coronavirus strains. Activities will include the following:

- \$195 million to conduct Phase 2/2b clinical trials. These costs would be to continue/expand existing clinical trials (ex. Remdesivir) and conduct new trials of other promising candidates.
- \$84 million to conduct preclinical evaluation and Phase 1 clinical trials of promising candidates.
- \$80 million for antiviral and monoclonal antibody discovery and development including screening of antiviral drug candidates using animal models. Funding will be provided through grants, contracts and support of intramural researchers.

### **Vaccines** (\$243 million)

Discovery and development of vaccine candidates to protect against COVID-19 and other coronaviruses. Activities include investigating antigen design strategies, novel platforms and/or delivery approaches, and adjuvants. Activity plans are broken out as follows:

- \$136 million to conduct Phase 2/2b clinical trials. These costs would be to continue/expand existing trials and support of vaccine candidates (ex. the NIAID Vaccine Research Center and Moderna mRNA platform candidate) and begin clinical trials of additional promising candidates.
- \$42 million to conduct preclinical evaluation and Phase 1 clinical trials of promising candidates.

- \$65 million to support vaccine development and discovery in NIAID Intramural labs and the extramural community.

## National Institute for Environmental Health Sciences

### Planned Activities – NIEHS

For decades, the NIEHS Worker Training Program's (WTP) Hazardous Waste Worker Training Program (HWWTP) and Hazmat Disaster Preparedness Training Program (HDPTP) has supported the development and dissemination of health and safety training to prepare workers to respond to, and perform day-to-day activities that have the potential for, exposure to hazardous pathogens, including H5N1 (bird flu), weaponized anthrax (post 9/11/2001), the global H1N1 pandemic, the 2014 Ebola outbreak and the current COVID-19 crisis. Training provided through cooperative agreements (grants) to a nationwide network of nonprofit and academic consortia creates a national resource of hazmat trainers and subject matter experts allowing the program to augment prevention and preparedness efforts in a wide variety of high-risk settings and in multiple geographic locations. During prior infectious disease outbreaks, the NIEHS WTP has enhanced the safety and health training of emergency responders, healthcare, correctional facilities, sanitation, transportation, mortuary, teachers, and other workers to ensure that responders are aware of site-specific hazards and mitigation techniques prior to and during response activities.

NIH/NIEHS Worker Training Program will continue to closely coordinate across HHS and the U.S. Government (USG), as well as with State, Local, Tribal, and Territorial (SLTT) and private sector partners, to ensure that activities funded through the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*, are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect the health of COVID-19 responders.

This plan describes planned activities for a total of \$10 million included for NIH/NIEHS in the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*.

#### Grant supplements (\$9 million over 3 years)

- Review and award of current and future grant applications through both supplemental awards and competitively peer-reviewed awards which address activities that are directly supporting the development and dissemination of safety and health training to prepare and build response worker capacity to address activities associated with control and prevention of COVID-19 illnesses and deaths.

#### Administrative support (\$1 million)

- Contract and grant oversight support of extramural COVID-19 training response activities.

# PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND

## Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020

(Dollars in millions)

Activity	Amount
Assistant Secretary for Preparedness and Response	2,798.000
<i>Medical Countermeasure Development</i>	
<i>Therapeutics</i>	666.130
<i>Vaccines</i>	983.351
<i>Diagnostics</i>	40.519
<i>Strategic National Stockpile (SNS)</i>	710.000
<i>Health Care Surge and Response Operations</i>	398.000
Health Resources and Services Administration – Health Centers	100.000
Additional Contingency Funds for Product Purchases <sup>1</sup>	300.000
Other Preparedness and Response Activities	200.000
Office of Inspector General (OIG)	2.000
<b>Total, PHSSEF Coronavirus Funding</b>	<b>3,400.000</b>

<sup>1</sup>The planned activities described below do not include this contingency funding which is available upon Congressional notification.

This plan reflects the allocation and planned uses of resources for the Public Health and Social Services Emergency Fund (PHSSEF) appropriation. Within the total of \$3.4 billion, \$2.8 billion will fund the Assistant Secretary for Preparedness and Response (ASPR) to support immediate preparedness for and response to the current COVID-19 outbreak. ASPR funding will specifically support Medical Countermeasure (MCM) development, Strategic National Stockpile (SNS) procurements, health care system preparedness, and emergency management. These efforts include identifying promising therapeutics and vaccines and advancing them towards licensure.

PHSSEF funding will also support enhanced services in existing health centers funded by the Health Resources and Services Administration (HRSA), as well as other preparedness and response activities across the Department. The areas of investments described below were instrumental in the response to the H1N1 Influenza Pandemic and the Ebola epidemic. This is the third coronavirus to emerge in less than 20 years, and unlikely to be the last.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Preparedness and Response Supplemental Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

## **Planned Activities – Assistant Secretary for Preparedness and Response**

### **Medical Countermeasure Development** (\$1,690 million)

- **Therapeutics** (\$666 million for development/domestic manufacturing capacity): Addressing the COVID-19 outbreak requires procuring and developing therapeutics for individuals that are severely ill, as well as developing therapeutics for individuals that have mild/moderate disease to prevent them from progressing to severe disease. It also requires consideration for supply chain and domestic manufacturing to ensure availability of the drugs once they are successfully developed. Underpinning this strategy is the need to develop these therapies as quickly as possible, including using platform technologies, focusing on potential therapies that have previous clinical data, and running as many tasks in parallel as possible to expedite development. Activities that would be funded include:
  - Screen existing monoclonal antibodies developed for other coronaviruses and development of new targeted monoclonal antibodies using platform technology that has been used to successfully license monoclonal antibodies for other diseases.
  - Advance two targeted monoclonal platform candidates identified in screening through manufacturing, non-clinical, and Phase 2 clinical trials.
  - Screen thousands of small molecule compounds with existing clinical data for activity against SARS-CoV-2.
  - For successful leads identified in the screening activity, support the (estimated) two to four lead small molecule candidates through the manufacturing, non-clinical, and early clinical development pipeline. The focus will be on oral small molecules that are appropriate for individuals with mild/moderate disease to prevent their progression to severe disease.
  - Expand domestic production capacity to ensure ability to rapidly produce meaningful amounts of therapeutics to respond to the outbreak.
  - Support initial advanced manufacturing to enable the establishment of new partnerships to accelerate advanced domestic manufacturing concepts for pharmaceutical and biopharmaceutical products. BARDA has been working closely with FDA to explore modern drug manufacturing processes that include advanced and continuous manufacturing. These advanced, modern processes can be further developed for implementation in the U.S. This reduces our reliance on foreign suppliers, will improve drug quality, and access, and ultimately enhance national security.
- **Vaccines** (\$983 million for development/domestic manufacturing capacity): Currently, there are no vaccines to prevent COVID-19 infection. Funds will support advanced development of up to five candidate coronavirus vaccines, including one or more that would be supported through Phase 2 and 3. ASPR will focus on vaccines that use established platform technologies. Equally important will be ensuring sufficient manufacturing capacity such that vaccine can be produced in meaningful quantities as soon as possible. Activities that would be funded include:
  - Advanced development of coronavirus vaccine utilizing vaccine platforms that support rapid development. (Estimated) four platforms will initially be funded with funding being shifted to those candidates that have the most promising data during



the development process. Funding will be sufficient to advance lead candidates into clinical trials.

- Support limited domestic manufacturing increase focused on vaccines being developed specifically for COVID-19.
- Funding of novel vaccine approaches and platforms to accelerate vaccine availability, delivery, and administration. This includes innovative vaccine platforms, and alternative delivery approaches to address a potential shortage of needles and syringes.
- Diagnostics (\$40 million): Currently, there are no point-of-care diagnostics available for COVID-19, either FDA-cleared or for use under Emergency Use Authorization (EUA). The only test currently available under EUA to diagnose COVID-19 infection is the CDC's test, and it is only available in CDC, Public Health, and some DoD labs. The funds will support development of assays to ensure ready availability of diagnostics for use in laboratories and other healthcare settings and near patient point of care to detect COVID-19 infection. Activities that would be funded include:
  - FDA clearance of multiple (estimated three to four) different assays for COVID-19 infection that span the breadth of diagnostic capabilities, from high-through put devices in commercial clinical labs, to large point of care, yet portable to handheld point of care.
  - Additional investment in availability of small handheld molecular diagnostics platforms suitable for use in non-traditional settings like screening stations.
  - Limited development of innovative next generation diagnostics to support an even more rapid, less invasive diagnostic capability.

#### Strategic National Stockpile (SNS) (\$710 million)

- The majority of new funds will be used to increase personal protective equipment (PPE) production capacity and slowly receive product into Strategic National Stockpile (SNS) inventory as excess becomes available beyond commercial market demands.
- SNS will also purchase ventilators, as well as circuits and other ancillary supplies, for sustained treatment of patients with secondary pneumonia which may be available for near term delivery.
- The volume of product represented by this amount of new PPE requirements will significantly increase the storage space required for SNS assets. Additional warehouse space will be required to hold the increased volume of SNS product, exceeding planned FY 2020 warehousing and storage costs.

#### Health Care Surge and Response Operations (\$398 million)

- Health Care Surge: ASPR will provide funds to private sector health care systems to support the urgent preparedness and response needs of hospitals, health systems, and physicians and nurses on the front lines of this outbreak in order to help prepare them to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens or persons under investigation for such an illness. The following activities are proposed:
  - National Ebola and Special Pathogens Training and Education Center (NETEC): Funds will support training and education of health care workers on COVID-19 and highly pathogenic infectious diseases. NETEC will develop specific training

for public health and health care workers to respond to COVID-19 as well as consultations and resources to assess health care facility readiness for this emerging infectious disease, including development of readiness metrics/measures.

- Regional, State and Local Special Pathogen Treatment Centers: Funds will support ten regional centers preparedness and response activities related to COVID-19. Activities include:
  - Conduct ten to 20 regional training summits (one to two per region) for frontline health care facility workers and awareness trainings to health care entities outside the acute health care system (e.g., home health agencies, residential placement facilities, behavioral health facilities, outpatient care facilities including specialty practices, long term care facilities, etc.)
  - Develop and implement a 24-hour hotline and other resources to support clinical consultation and technical assistance for COVID-19 (e.g., telemedicine)
- State Hospital Associations: ASPR will provide targeted awards to state hospital associations where there are cases of COVID-19. State hospital associations will distribute funds to hospitals in their states that are in the hospital catchment areas associated with known or suspected COVID-19 cases, which may be used for the following:
  - Quickly update and train staff to implement pandemic preparedness plans to respond to COVID-19
  - Procure supplies and equipment (with attention to supply chain shortages)
  - Rapidly ramp up infection control and triage training for health care professionals, especially in light of growing supply chain shortages
  - Retrofit separate areas to screen and treat large numbers of persons with suspected COVID-19 infections, including isolation facilities in or around hospital emergency departments to assess potentially large numbers of persons under investigation for COVID-19 infection
  - Plan, train, and implement expanded telemedicine and telehealth capabilities to ensure that appropriate care can be provided to individuals in their homes or residential facilities when social distancing measures are used to reduce virus transmission
  - Increase the numbers of patient care beds to provide surge capacity using temporary structures, such as temporary hospitals that are deployed in a pandemic.
- 62 HPP Formula-Based Cooperative Agreements: Through formula-based awards, the 62 HPP recipients will initiate the following activities over the next 6 months:
  - Support the 44 state or jurisdiction Ebola treatment centers to focus preparedness and response efforts on COVID-19
  - Support health care coalition (HCC) participation in training and educational opportunities offered at the regional/state/local level to enhance knowledge of health care intervention, treatment, and mitigation activities associated with COVID-19

- Augment surveillance systems to provide expanded capability to assess and respond to health care system stress associated with patient surge
  - Provide supplemental staffing to initiate training/education and other associated activities.
  - Procure supplies and equipment (with attention to supply chain shortages)
- Field Operations and Emergency Management
    - Funds will be used to support medical team deployments, logistics, surge staffing, continuity of operations, and expanded information technology and communications for the SOC and Incident Management Team field components.
    - Funds also will be provided to ESF-8 (DoD, VA, DHS/FEMA) partners to provide assets for health and medical response missions. No funding authorized under the Stafford Act is assumed.
    - Funds also will be used to provide surge capability to hospitals and other healthcare facilities. Funds will procure fold out rigid temporary shelter systems that will expand deployable capabilities to protect vulnerable populations in large scale responses. These shelter systems will serve as drop in mobile medical facilities permitting a broad scope of medical capabilities in a sterile environment for emergent needs when local capacity is exhausted or inactive, with capacity to treat a number of indications to high levels of severity.
    - In addition, funds will procure high-acuity kits (HAK) to expand the capability of Federal Medical Shelters in the SNS to provide high levels of care to patients severely impacted by disease and respiratory distress.
    - Approximately \$40 million will fund salaries of intermittent employees deployed for response activities over the next six months as well as ongoing efforts to recruit intermittent responders.

## **Planned Activities – Health Resources and Services Administration**

### Health Centers (\$100 million)

- Health center supplemental grant awards
  - Formula based, supplemental grant awards to existing HRSA funded health centers.
  - Given the rapid recent spread of COVID 19 and the need for all health centers to be prepared to address this new coronavirus, HRSA plans to make resources available to all health centers across the country. This approach will allow health centers to implement universal precautions, testing, training, and/or purchasing needed screening equipment as quickly as possible. Awards will provide a base amount and an additional increase based on the number of patients served.
  - Awards will support enhanced services in existing health centers to prevent, prepare for, and respond to the national coronavirus emergency. Supplemental awards are projected to support health center preparedness activities, patient surge/enhanced services including testing and labs as appropriate, enhanced health information technology including telehealth, acquisition of supplies and personal protective equipment specific to preventing, testing for, and treating

coronavirus, and health center participation in community emergency preparedness activities.

### **Planned Activities – Other Preparedness and Response Activities (\$200 million)**

As the COVID-19 pandemic rapidly evolves and the number of cases across the world and domestically continue to grow, HHS continues to monitor the situation and support response activities supported with additional emergency supplemental resources. HHS continues to identify program flexibilities and is working to eliminate obstacles to help support front line responders and overall response activities. HHS continues to assess various potential additional activities to support with emergency supplemental resources, including but not limited to additional health care services, targeted coordination activities, and technical and infrastructure capacity to support preparedness and response.

#### **Additional Health Care Services (\$30 million)**

- Support for the initial infrastructure for the federal Community Based Testing Sites (CBTS), including initial support for a locator website to provide readily available information on testing options and locations; a call-center, to provide the public with testing results; and laboratory delivery and testing activities.
- Funds support medical review and eligible compensation of claims alleging injuries from covered countermeasures used to treat, diagnose and prevent coronavirus.

#### **Indian Health Service (\$70 million)**

- Funds support the purchase of personal protective equipment and medical supplies through the IHS National Supply Service Center. These resources will be available to IHS, Tribal, and Urban Indian health programs free of charge.
- Funds also support COVID-19 response activities for IHS Federal health programs, to complement funds provided from CDC to support Tribal health programs.

#### **Targeted Coordination Activities (\$42 million)**

- Funds support the improvement of government platforms for the surge dissemination of information, including the establishment of Coronavirus.gov FAQ website solution and continued maturation and integration of this site to provide sustainable and quick, accurate real-time answers to commonly asked questions.
- Funds also support the management and coordination of data modeling efforts ensuring cross agency/government collaboration, providing strategic analytic support and change management to enable program execution.
- A COVID-19 data-sharing platform has been established to coordinate efforts to collect and analyze sensitive data elements.

#### **Technical and Infrastructure Capacity to Support Preparedness and Response (\$55 million)**

- Funds support key network, systems and equipment upgrades to increase capacity and support personnel and systems during the public health emergency.
- Funds support surge personnel in programmatic and technical capacities.

## **Planned Activities – Office of Inspector General**

### **Office of Inspector General (OIG) Oversight** (\$2 million)

- A total of \$2 million will support the Office of Inspector General (OIG) to oversee HHS efforts to combat COVID-19, including oversight of the emergency supplemental funding provided to HHS's Operating Divisions. OIG reviews will help ensure proper oversight and management by HHS agencies, including oversight of expenditures for needed health and human services to combat COVID-19. This would include assessing the efficiency and effectiveness of HHS activities, grants, contracts, and providers. It would include assessing internal controls and procedures for ensuring the safety and provision of necessary resources to individuals or entities impacted by COVID-19.
- OIG typically obligates 4% as an organization on overhead/administration costs. OIG anticipates that work to support coronavirus preparedness and response will require a similar level of administrative costs.

# FOOD AND DRUG ADMINISTRATION

## Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020

(Dollars in millions)

Activity	Amount
Efforts Related to Potential Shortages	16.567
Enforcement work on counterfeit or misbranded products	2.102
Work on emergency use authorizations (EUAs)	2.962
Pre and post market work on medical counter measures, therapies, and vaccines and research	21.370
Advanced Manufacturing	18.000
<b>Total, FDA Coronavirus Funding</b>	<b>61.000</b>

### Planned Activities

#### Efforts Related to Potential Medical Products Shortages (\$16.567 million)

- FDA's Center for Biologics Evaluation and Research (CBER) activities include receipt and processing of responses and potential shortage notifications; coordination of expediting reviews and/or lot release to mitigate or prevent shortages; coordination with DHHS Vaccines for Children program, if needed; communication and coordination with international counterparts; and review of guidance, and inquiries from stakeholders. It includes operating costs for FTE such as travel for site visits, inspections and contract staff.
- FDA will expand tracking and monitoring systems, for use across the agency, to collect and analyze large amounts of data and share data securely. These systems will enable FDA to track shortages and supply chain challenges related to medical products.
- FDA's Center for Drug Evaluation and Research (CDER) will use the funding to address the most critical activities for our COVID-19 response. For FY 2020 and 2021, supplemental funds will be used to support operating costs, including a contract for a predictive modeling tool that incorporates multiple sources of data to analyze the drug supply chain and predict human drug shortages in the future. This tool will be used to address all human drug shortages, including those related to the current COVID-19 outbreak.
- FDA's Center for Veterinary Medicine (CVM) will develop an Animal Drug and Manufacturing System to readily retrieve information on animal drug products, active pharmaceutical ingredients, and the status of manufacturing sites. This database will allow CVM to quickly identify and address critical facilities and animal drugs impacted by emerging diseases or natural disasters and help to identify solutions to potential drug shortages and respond to customs importation requests. Funding for this system will be through a contract.
- FDA's Office of the Chief Scientist (OCS/OCET) will support regulatory science research to help foster the development and adoption of advanced manufacturing technologies to help prevent and mitigate potential product shortages to better meet the demands of pandemic or emergency response. Research that will be supported may include metrics and real-time assays to enable technology adoption through assessing and

validating continuous manufacturing and inline process controls relevant to COVID-19 medical countermeasures.

- FDA's Center for Devices and Radiological Health (CDRH) will use term and temporary employees to conduct outreach to manufacturers to request voluntary disclosure of information on essential devices in geographies impacted by COVID-19, devices associated with responding to COVID-19, and personal protective equipment. CDRH will conduct outreach to the health care delivery organizations. This funding also will support work to identify and mitigate potential device shortages by providing registration and device listing data, import entry data, and expert scientific and clinical consults on devices, their intended uses, and regulatory status.
- FDA's Office of Regulatory Affairs (ORA) will support efforts related to potential shortages through non-salary related expenses for performance of domestic/foreign inspections of viable manufacturers, pre-market/post-market inspections, import activities (such as screenings, entry review), and PPE for personnel performing their duties.
- This funding will also cover overtime costs for monitoring, reporting and coordinating FDA's activities to meet the needs of federal partners, advice on legal authority to monitor supply chains and respond to shortages and potential shortages, as well as help to develop, review, and clear guidance documents, other Federal Register documents, and agency-level communications.

#### Enforcement work on counterfeit or misbranded products (\$2.102 million)

- FDA's CBER will conduct internet and other surveillance to detect fraudulent COVID-19 products touted as biological products and take action as appropriate.
- FDA's CVM will utilize a contract to develop a system to retrieve information on animal drug products, including import and sales information, to quickly identify false and/or misleading claims regarding the use of unapproved animal drug to mitigate the emerging disease (such as coronavirus) or other related benefits to either humans or animals, and aide in FDA compliance actions.
- FDA's CDRH will closely monitor and prioritize allegations of misbranded and adulterated devices with a focus on devices used to diagnose or care for COVID-19 patients.
- FDA's ORA will support the issuance of import screening associated with products and manufacturers affected by impacts of COVID-19 on FDA operations and inspections. ORA also will support health fraud investigational related activities such as purchase of undercover/anonymous browser software and health fraud laptops, sample purchasing, and laboratory analysis.
- This funding will enhance infrastructure capabilities at the FDA International Mail Facilities sites. This infrastructure is crucial to support FDA import screening facilities and FDA enforcement work on counterfeit or misbranded products.
- This funding will also support the review of FDA Warning and Untitled Letters for legal sufficiency and provide legal support on all proposed enforcement actions.

#### Work on emergency use authorizations (EUAs) (\$2.962 million)

- FDA's CBER will support EUAs, including operating costs for global harmonization and enhancing standards development to support EUAs.

- FDA's CDRH will work closely with firms who may submit EUA requests for personal protective equipment (PPE), medical devices used in cleaning/disinfection/sterilization, and a large number of diagnostic devices.
- This funding will also increase infrastructure storage and computing power capabilities to facilitate FDA work on EUAs across the agency.
- FDA's OPLIA will process and ensure publication of all EUAs in the Federal Register. OPLIA also will engage with Congress and advise senior FDA officials on Congressional views on FDA's work on EUAs.
- This funding will support the review and critical legal advice on all proposed EUAs. OCC also will work with HHS OGC to obtain necessary Secretarial determinations and declarations and provide legal advice on associated Public Readiness and Emergency Preparedness (PREP) Act issues.

Pre and post market work on medical counter measures, therapies, and vaccines and research  
(\$21.370 million)

- FDA's OCS/OCET will support regulatory science research to help facilitate the development and regulatory review of investigational medical products for COVID-19 caused by SARS-CoV-2. This includes research to support:
  - Developing correlates of protection to aid in understanding the safety and effectiveness of COVID-19 medical countermeasures
  - Characterizing the interactions between SARS-CoV-2 and humans or animals to support the development of assays for COVID-19 pathology to help the generation of data to support medical countermeasure development
  - Assessing the stability of SARS-CoV-2 during disease as well as in comparison to other coronaviruses to ensure that antibody and vaccine targets pursued for medical countermeasure development are valid and stable.
- FDA's CBER will conduct research projects and support (including purchases of equipment and supplies and contract research staff) in FY 2020 and 2021 for development of:
  - (2019-nCoV) Coding Domain Sequence: In Silico Analysis and Evaluation
  - technologies for evaluation of antibody response following Coronavirus infection and vaccination to identify immune correlates of protection
  - high-throughput neutralization assays for pathogenic human coronaviruses
  - permissive cell lines for COVID-19 titration and neutralization assays, and evaluation of protective antibodies in human sera
  - Reference Materials to Evaluate Molecular Diagnostic Devices for 2019-nCoV evaluation of protective immunity induced by 2019 Novel Coronavirus (2019-nCoV)
  - assay to measure nCoV binding/neutralizing antibodies in human plasma and immune globulins
  - evaluation of the efficacy and specificity, as well as cellular effects, of CRISPR-mediated inhibition of RNA viruses
- FDA's CBER also will support configuration of foundational surveillance systems to capture data associated with coronavirus. This includes efforts to potentially track the course of the disease in the US to inform decisions concerning blood, tissue and biologic



product donor eligibility, deferrals and to conduct foundational work to build postmarket safety and effectiveness surveillance systems for any preventative vaccines or therapeutics.

- FDA's Center for Food Safety and Applied Nutrition (CFSAN) is partnering with the FDA Office of Counterterrorism and Emerging Threats to use the agency's expertise in food virology to address questions about the safety of food that may have been exposed to coronavirus. FDA is finalizing contract support to study the environmental stability of SARS-CoV-2 on food and food packaging, as well as whether the virus is infectious via oral exposure to contaminated food.
- FDA's CDRH will support medical countermeasures, including work with DoD on approaches to closed loop technologies necessary for austere environments and working with BARDA on industry proposals for development of device countermeasures for CBRN and infectious diseases.
- FDA's CDRH will also use funding to review premarket files for new and modified devices, especially personal protective equipment (PPE), medical devices used in cleaning/disinfection/sterilization, and a large number of diagnostic devices. CDRH's premarket work will support the review of devices for COVID-19 responses and post-market work will involve close monitoring of adverse event reports related to devices used to diagnose or care for COVID-19 patients. In addition, current methods are laborious and require specialized equipment. CDRH will use this funding to develop rapid and accurate tests that can be used in a QC setting for the effectiveness of PPE, particularly gowns and other barriers.
- FDA's ORA will cover non-salary related expenses for recall audit checks (RACs), Pre-approval inspections (PAIs), medical counter measures, import screenings, and entry review. These funds will help to support domestic/foreign travel costs, supplies for laboratory analysis, sample purchasing, equipment purchases, and PPE. Funds also will support improving program assignment code (PAC) creation and management to allow rapid deployment of PACs used for reporting COVID-19 work as well as reporting future outbreaks and assignments.
- FDA's National Center for Toxicological Research (NCTR) will evaluate the SARS-CoV-2 regulatory science gaps to help combat and stop the current outbreak. Centers with Biosafety Level (BSL)-3 facilities are currently engaged in growing the virus and studying virus pathogenesis, inactivation and environmental persistence. NCTR's contribution to this effort will be a two-year study at a BSL-2 level by producing a recombinant SARS-CoV-2 spike, hyperimmune serum and study cell receptor to this virus. Reagents generated through this study can be supplied to Biodefense and Emerging Infections Research (BEI) resources and other labs to speed the knowledge gained on this virus. Identification of the virus receptor will help design drugs to treat SARS-CoV-2 infection or prevention on exposed individuals.
- FDA will enhance analytical capabilities by leveraging scalable cloud technologies to provide and distribute computing power. FDA will leverage data and AI capabilities to scale research and surveillance beyond current capabilities.
- This funding will be used to develop, review, and clear guidance documents, other Federal Register documents, and agency-level communications, as well as provide legal advice on investigational products, clinical trials, export, enforcement discretion and associated PREP Act issues.

### Advanced Manufacturing (\$18.000 million)

- FDA will establish a Center of Excellence for Advanced Manufacturing to enhance research efforts and provide training in advanced manufacturing for improving FDA's readiness in evaluating new manufacturing technologies for drugs and vaccines, cell and gene therapies, and other biologics. This is a collaborative effort between the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).
- The funding will bolster FDA's regulatory programs and establish new strategies and approaches to advance the regulatory framework, quality management system maturity, and lifecycle management in support of a broader adoption of advanced manufacturing.
- Further support the development of technologies for the advanced manufacture of recombinant vaccines, which can result in more agile and efficient manufacturing of critical vaccines to help address emerging infections such as pandemic influenza and novel infectious diseases. These technologies include the development of better cell lines (i.e., cell lines with the potential for higher yields) and improved bioreactors for vaccine production.
- Launch the Medical Device Information Analysis and Sharing System (MDIAS) version 1.0 and establish an independent clearing house program for medical device advanced manufacturing.

**Department of Health and Human Services**

**Second Coronavirus Preparedness and Response Supplemental  
Appropriations Act, 2020 Spend Plan - UPDATE  
1<sup>st</sup> 60-day Update to Congress**

/JEN MOUGHALIAN/

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Jen Moughalian  
Principal Deputy Assistant Secretary

## INTRODUCTION

The Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 in the Family First Coronavirus Response Act, enacted March 18, 2020 (P.L. 116-127), provided \$1.314 billion in emergency supplemental funding to the Department of Health and Human Services (HHS) for Coronavirus preparedness and response activities. The Act allocated \$64 million to the Indian Health Service (IHS), \$250 million to the Administration for Community Living (ACL), and \$1.0 billion to the Public Health and Social Services Emergency Fund (PHSSEF). This report provides the first 60-day update submitted to the Committees as requested in the Section 1701 reporting requirements below. This report includes any updates to the summary table providing Department-wide totals.

The reporting requirements within Section 1701 of the Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-127) states:

SEC. 1701. Not later than 30 days after the date of enactment of this Act, the head of each executive agency that receives funding in this Act shall provide a report detailing the anticipated uses of all such funding to the Committees on Appropriations of the House of Representatives and the Senate: Provided, That each report shall include estimated personnel and administrative costs, as well as the total amount of funding apportioned, allotted, obligated, and expended, to date: Provided further, That each such plan shall be updated and submitted to such Committees every 60 days until all funds are expended or expire.

**Second Coronavirus Preparedness and Response Supplemental  
Appropriations Act, 2020 Spend Plan - UPDATE  
(as of June 4<sup>th</sup>, 2020)**

As of June 4th, 2020, the Department of Health and Human Services (HHS) is reporting no changes to activities reported in the original spend plan of the \$1,314 million appropriated in the Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 in the Family First Coronavirus Response Act, enacted March 18, 2020 (P.L. 116 127).

To respond to the growing global presence of COVID-19, the United States has supported a government-wide response to combat the virus and limit the negative health outcomes which can result. HHS has and continues to work with partners across the Federal government, states, and the private sector. Activities include aiding domestic and international public health preparedness and response efforts; conducting public health surveillance, epidemiology, and laboratory testing; quarantining individuals who pose a risk of transmitting the virus; training health care workers; advancing the development, testing, and availability of new vaccines, therapeutics, and diagnostics; advancing manufacturing enhancements; procuring and deploying necessary medical supplies following required notification; and providing social services and supports to at-risk populations such as older adults, American Indians/Alaska Natives, and children. Building on activities funded under the first COVID-19 Supplemental, funding appropriated to HHS under the Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 will support activities across the Department to enhance ongoing efforts and continue a comprehensive and coordinated response to contain and mitigate COVID-19.

**HHS Coronavirus Supplemental Funding Spend Plan**  
*(dollars in millions)*

<b>Budget Activity</b>	<b>HHS Supplemental Funding</b>
<b><u>Indian Health Service</u></b>	<b>64.0</b>
<i>Urban Indian Organizations</i>	3.0
<i>IHS- and Tribally-Operated Health Programs</i>	61.0
<b><u>Administration for Community Living</u></b>	<b>250.0</b>
<i>Congregate Nutrition Services</i>	80.0
<i>Home-Delivered Nutrition Services</i>	160.0
<i>Native American Nutrition and Supportive Services</i>	10.0
<b><u>Public Health and Social Services Emergency Fund</u></b>	<b>1,000.0</b>
<i>Health Resources and Service Administration – Claims Processing Services for COVID-19 Uninsured</i>	1,000.0
<b>Total, HHS Coronavirus Supplemental Funding</b>	<b>1,314.0</b>

**Indian Health Service  
Second Coronavirus Preparedness and Response  
Supplemental Appropriations Act, 2020**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
COVID-19 Testing	64.000
<i>Urban Indian Organizations (non-add)</i>	<i>3.000</i>
<i>IHS- and Tribally-Operated Health Programs (non-add)</i>	<i>61.000</i>
<b>Total, IHS Coronavirus Funding</b>	<b>64.000</b>

HHS is closely coordinating across the Department to ensure that activities funded through the Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$64 million included for IHS in the Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. These funds will support the cost of COVID-19 testing across the Indian Health System. Funds will be provided to Urban Indian Health Organizations, and to IHS- and Tribally- operated health programs, through existing funding mechanisms.

**Planned Activities**

COVID-19 Testing (\$64 million) –

- Funds to offset the cost of COVID-19 testing for IHS- and Tribally- operated health programs, and Urban Indian Organizations.
- Funds will be provided through well-established funding mechanisms for distributing resources across the full Indian health system.
- These funds can support the tests, as well as the material needed to provide the test, and all other costs associated with the patient visit that results in the COVID-19 test.
- IHS will not reserve administrative costs from this funding at the Headquarters or Area level, given that the purpose of the funds is specifically for COVID-19 testing and related costs.

**Administration for Community Living  
Second Coronavirus Preparedness and Response  
Supplemental Appropriations Act, 2020**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Congregate Nutrition Services	80.000
Home-Delivered Nutrition Services	160.000
Native American Nutrition and Supportive Services	10.000
<b>Total, ACL Coronavirus Funding</b>	<b>250.000</b>

ACL nutrition services programs provide funding to States and Tribal Organizations for the delivery of meals and related services to older adults in their homes and in a variety of community settings (e.g., senior centers, churches, community centers, congregate dining facilities, school and hospital cafeterias). The need for these services, particularly home-delivered and packaged meals, has significantly increased as community measures to slow transmission of COVID-19 have closed meal sites and have left many family caregivers unable to assist their older loved ones.

A total of \$250 million is provided under the Second Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 to help meet these needs. ACL anticipates that States will use funding both to expand the number of home-delivered meals and to provide alternatives, such as drive-by or grab-and-go meals, in place of meals that would normally be consumed in congregate settings. Funds are awarded as formula grants to States, giving them maximum flexibility to determine the best approaches to serving seniors in need. None of the supplemental funding will be used to support either Federal administration or Federal Full Time Equivalent (FTE).

HHS is closely coordinating across the Department to ensure that activities funded through the Second Coronavirus Preparedness and Response Supplemental Act, 2020 are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$250 million included for ACL in the Second Coronavirus Preparedness and Response Supplemental Act, 2020.

**Planned Activities**

Congregate Nutrition Services (\$80 million) –

- Formula grant awards will allow States to provide meals and related services to older adults age 60 and older through existing Congregate Nutrition programs, which could include “drive-through” or “grab-and-go” meals. This will help to ensure adequate nutrition for seniors who typically would participate in meal programs at congregate sites

that have been closed due to social distancing measures or who are limiting their exposure to the coronavirus by avoiding supermarkets, restaurants, and other venues where food would normally be available.

Home-Delivered Nutrition Services (\$160 million) –

- Formula grant awards will allow States to deliver meals and related services directly to older adults age 60 and older. This could include both frail seniors and those needing to remain in their homes to avoid the risk of contracting the virus.

Native American Nutrition and Supportive Services (\$10 million) –

- Formula grant awards will allow Tribes and Tribal Organizations to provide meals and related services directly to Native American elders, whose access to meals have been restricted by the coronavirus, in the most appropriate setting during this public health emergency.



**Health Resources and Services Administration  
Second Coronavirus Preparedness and Response  
Supplemental Appropriations Act, 2020**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Claims Processing Services for COVID-19 Uninsured	1,000.000
<b>Total, HRSA Coronavirus Funding</b>	<b>1,000.000</b>

HHS is closely coordinating across the Department to ensure that activities funded through the Second Coronavirus Preparedness and Response Supplemental Act, 2020 are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$1 billion appropriated to the Public Health and Social Services Emergency Fund in the Second Coronavirus Preparedness and Response Act, 2020 to be carried out by HRSA.

**Planned Activities**

Claims Processing for COVID-19 Uninsured (\$996.6M) –

Funding will support a contract to provide end-to-end claims processing services to reimburse physician practices, clinics, health care centers, hospitals, labs, and any health care entity that provides COVID-19 testing to uninsured patients. The contractor will manage the funding for the Testing for the Uninsured in coordination and alignment with the Treatment for the Uninsured activities funded through the Provider Relief Fund. The COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program funding will cover reimbursement for the following testing-related services:

- *In vitro* diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and the administration of such products that
  - are approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb-3);
  - the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;
  - is developed in and authorized by a State that has notified the Secretary of

Health and Human Services of its intention to review tests intended to diagnose COVID-19; or

- other test(s) that the Secretary determines appropriate in guidance.
- Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an *in vitro* diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product and to the provision of the test results to the patient if a test was administered.

**Program Administration – (\$3.4M)**

- Costs to facilitate the administration of this emergency supplemental funding to include contract management, financial management, FTE, and claims payment review, validation, and processing.

**Department of Health and Human Services**

**Coronavirus Aid, Relief, and Economic Security (CARES) Act Spend Plan**

**April 28, 2020**

/JEN MOUGHALIAN/

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Jen Moughalian

Principal Deputy Assistant Secretary

## INTRODUCTION

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, enacted March 27, 2020 (P.L. 116-136), provided \$142.833 billion in emergency supplemental funding to the Department of Health and Human Services (HHS) for Coronavirus preparedness and response activities.

The Act allocated \$1.3 billion to the Health Resources and Services Administration, \$80 million for the Food and Drug Administration (FDA), \$1 billion for the Indian Health Service (IHS), \$12.5 million for the Agency for Toxic Substances and Disease Registry, \$4.3 billion to the Centers for Disease Control and Prevention (CDC), \$945.4 million to the National Institutes of Health (NIH), \$425 million to the Substance Abuse and Mental Health Services Administration (SAMHSA), \$200 million for the Centers for Medicare & Medicaid Services, \$6.3 billion to the Administration for Children and Families (ACF), \$955 million to the Administration for Community Living (ACL), and \$127.3 billion to the Public Health and Social Services Emergency Fund (PHSSEF).

The reporting requirements within Section 18112 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) states:

SEC. 18112 – Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall provide a detailed spend plan of anticipated uses of funds made available to the Department of Health and Human Services in this Act, including estimated personnel and administrative costs, to the Committees on Appropriations of the House of Representatives and the Senate: *Provided*, That such plans shall be updated and submitted to such Committees every 60 days until September 30, 2024. *Provided further*, that the spend plans shall be accompanied by a listing of each contract obligation incurred that exceeds \$5,000,000 which has not previously been reported, including the amount of each such obligation.

The following spend plan details the planned uses of the supplemental funds appropriated to HHS. With these resources, HHS will support a comprehensive response to the COVID-19 outbreak, including expansions of domestic and international preparedness and response activities; accelerated development, testing, and availability of vaccines, therapeutics, diagnostics, and necessary medical supplies; and critical investments in public health capacity and social services to ensure State, local, and Federal entities are able to prepare for, prevent, and respond to COVID-19 and its impact on the health and safety of the American public.

## HHS OVERVIEW

To respond to the growing global presence of COVID-19, the United States has supported a government-wide response to combat the virus and limit the negative health outcomes which can result. HHS has worked, and continues to work, with partners across the Federal government, the states, and the private sector. Activities include aiding domestic and international public health preparedness and response efforts; conducting public health surveillance, epidemiology, and laboratory testing; quarantining individuals who might have been exposed to the virus and isolating those who contracted the virus; training health care workers; advancing the development, testing, and availability of new vaccines, therapeutics, and diagnostics; advancing manufacturing enhancements; procuring and deploying necessary medical supplies; and providing social services and supports to at-risk populations such as older adults, persons with disabilities, American Indians/Alaska Natives, children, and individuals with substance use disorders.

Building on activities funded under the first and second COVID-19 supplementals, funding appropriated to HHS under the Coronavirus Aid, Relief, and Economic Security (CARES) Act, will support activities across the Department to enhance ongoing efforts and continue a comprehensive and coordinated response to address the impact of COVID-19.

### HHS Supplemental Funding Spend Plan, CARES Act *(dollars in millions)*

Budget Activity	HHS Supplemental Funding
<b><u>Health Resources and Services Administration</u></b>	<b>1,320.0</b>
<i>Health Centers</i>	<i>1,320.0</i>
<b><u>Food and Drug Administration</u></b>	<b>80.0</b>
<b><u>Indian Health Service</u></b>	<b>1,032.0</b>
<i>Allocation to IHS, Tribal, and Urban Indian Health Programs</i>	<i>600.0</i>
<i>Electronic Health Record Stabilization and Support</i>	<i>65.0</i>
<i>Allocated at Discretion of the IHS Director</i>	<i>367.0</i>
<b><u>Centers for Disease Control and Prevention</u></b>	<b>4,312.5</b>
CDC	<b>4,300.0</b>
<i>Domestic Cooperative Agreements</i>	<i>1,500.0</i>
<i>Public Health Response and Preparedness</i>	<i>1,500.0</i>
<i>Public Health Data Surveillance and Analytics Infrastructure</i>	<i>500.0</i>
<i>Global Disease Detection and Emergency Response</i>	<i>500.0</i>
<i>Infectious Diseases Rapid Response Reserve Fund</i>	<i>300.0</i>
ATSDR	<b>12.5</b>
<i>Geospatial Research, Analysis and Services</i>	<i>7.5</i>

<i>Pediatric Environmental Health Specialty Units</i>	5.0
<b><u>National Institutes of Health</u></b>	<b>945.4</b>
<i>National Institute of Allergy and Infectious Diseases</i>	706.0
<i>National Heart, Lung, Blood Institute</i>	103.4
<i>National Institute of Biomedical Imaging and Bioengineering</i>	60.0
<i>National Library of Medicine</i>	10.0
<i>National Center for Advancing Translational Sciences</i>	36.0
<i>Office of the Director</i>	30.0
<b><u>Substance Abuse and Mental Health Services Administration</u></b>	<b>425.0</b>
<i>Certified Community Behavioral Health Clinics</i>	250.0
<i>State Emergency Response Grants</i>	110.0
<i>Suicide Prevention Programs</i>	50.0
<i>Tribal Response</i>	15.0
<b><u>Centers for Medicare &amp; Medicaid Services</u></b>	<b>200.0</b>
<i>Survey and Certification</i>	100.0
<b><u>Administration for Children and Families</u></b>	<b>6,274.0</b>
<i>Low Income Home Energy Assistance</i>	900.0
<i>Child Care Development Block Grant</i>	3,500.0
<i>Community Services Block Grant</i>	1,000.0
<i>Head Start</i>	750.0
<i>Domestic Violence Hotline</i>	2.0
<i>Family Violence Prevention and Services</i>	45.0
<i>Runaway and Homeless Youth</i>	25.0
<i>Child Welfare Services</i>	45.0
<i>Federal Administrative Expenses</i>	7.0
<b><u>Administration for Community Living</u></b>	<b>955.0</b>
<i>Home-Delivered Nutrition Services</i>	480.0
<i>Native American Nutrition and Supportive Services</i>	20.0
<i>Home and Community-Based Supportive Services</i>	200.0
<i>Family Caregiver Support Services</i>	100.0
<i>National Long-Term Care Ombudsman Program</i>	20.0
<i>Aging and Disability Resource Centers</i>	50.0
<i>Centers for Independent Living</i>	85.0

<b><u>Public Health and Social Services Emergency Fund</u></b>	<b>127,289.5</b>
<i>Assistant Secretary for Preparedness and Response</i>	25,090.0
<i>Health Resources and Service Administration</i>	275.0
<i>Office of the Inspector General</i>	4.0
<i>NASEM Study of Medical Product Supply Chain</i>	1.5
<i>Other Federal Agencies</i>	289.0
<i>Provider Relief and Protection Fund</i>	100,000.0
<b>Total, HHS Coronavirus Supplemental Funding</b>	<b>142,833.4</b>

## HEALTH RESOURCES AND SERVICES ADMINISTRATION

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

Activity	Amount
Health Centers	1,320.000
<b>Total, HRSA Health Centers Coronavirus Funding</b>	<b>1,320.000</b>

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provides the HRSA Health Center program \$1.3 billion in mandatory resources.

HHS is closely coordinating across the Department to ensure that activities funded through the CARES Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities to be carried out by the HRSA Health Center program in the Coronavirus Aid, Relief, and Economic Security Act.

#### Planned Activities

##### Health Centers (\$1,320.0 million)

- Health center supplemental grant awards (\$1,316.0 million)
  - Formula based, supplemental grant awards to existing HRSA funded health centers.
  - Given the rapid recent spread of SARS-CoV-2 and the need for all health centers to be prepared to address COVID-19, HRSA plans to make resources available to all health centers across the country. Awards will provide a base amount and an additional increase based on the total number of patients served and the number of uninsured patients served.
  - Awards will support enhanced services in existing health centers for the detection of SARS-CoV-2 and for the prevention, diagnosis, and treatment of COVID-19, including costs of maintaining or increasing health center capacity and staffing levels. Supplemental awards are projected to support health center preparedness activities, patient surge/enhanced services including testing and treatment as appropriate, minor facility alteration and renovation, enhanced health information technology including telehealth, acquisition of supplies and personal protective equipment specific to preventing, testing for, and treating Coronavirus, health center participation in community emergency preparedness activities, and the provision of primary health care services to reduce the burden on the nation's emergency rooms and hospitals in areas impacted by Coronavirus.
- Program administration (\$4.0 million)
  - Funding will support the administration of the emergency supplemental grant award process, including monitoring and oversight of health center activities.



Also supported are costs associated with IT system enhancements such as to support Coronavirus-related reporting, and analyses of activities supporting the alteration and renovation of health center facilities, including environmental and architectural/engineering analysis.

## FOOD AND DRUG ADMINISTRATION

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

Activity	Amount
Efforts Related to Potential Medical Product Shortages	38.300
Enforcement Work on Counterfeit or Misbranded Products	2.200
Work on Emergency Use Authorizations	4.800
Pre and Post Market work on Counter Measures, Therapies, and Vaccines	30.000
Operational Costs	4.600
<b>Total, FDA Coronavirus Funding</b>	<b>80.000</b>

The US Department of Health and Human Services (HHS) is closely coordinating across the Department to ensure that activities funded through the Coronavirus Aid, Relief, and Economic Security (CARES) Act, 2020, PL 116-136 are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

FDA continues to participate in interagency COVID-19 prioritization and coordination activities. This plan describes the activities that FDA plans to undertake with the \$80.0 million provided in the Coronavirus Aid, Relief, and Economic Security Act. As many of these activities have also been funded with the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, PL 116-123, the descriptions of the planned activities are focused on new activities or continuations of the activities started under PL 116-123, as appropriate.

### **Planned Activities**

#### Efforts Related to Potential Medical Product Shortages (\$38.3 million)

- Implement governance and project management to enhance the coordination of drug supply chain initiatives and develop IT requirements
- Invest in acquiring data, conducting research and developing analytic methodologies to identify products at risk of a drug shortage and conduct other supply chain vulnerability assessments
  - Continue to fund travel for critical site visits and inspections related to potential shortages
  - Enhance existing animal drug post-approval data collection system to effectively capture and analyze animal drug sales information to quickly and effectively address potential drug shortages and to support other critical program areas
  - Enhance reviewer training in advanced manufacturing tools, provide outreach to sponsors to gain perspective from regulated industry, and develop a formal process for reviewers accompanying ORA investigators on pre-approval inspections
  - Continue to conduct extensive outreach to manufacturers and support work to identify and mitigate potential device shortages
  - Manage and mitigate existing identified medical device shortages

- Conduct horizon scanning to identify important devices with vulnerable supply chains or otherwise likely to be at high risk of potential shortage as COVID-19 progresses and further impacts the US and global supply chain
- Determine the supply chain for important devices, get information about manufacturing capacity and impact of COVID-19 on supply, manufacturing, and distribution;
- Assess the impact of increased demand for certain medical products due to COVID-19 and develop and deploy regulatory actions and other measures to mitigate these shortages
- Enhance our understanding of current non-contact infrared (IR) thermometers and the development of newer techniques for non-contact measurement of patients' vital signs
- Support non-salary related expenses for performance of additional domestic/foreign inspections of viable manufacturers, pre-market/post-market inspections, import activities (screenings, entry review, etc.), drug shortage related inspections, and Personal Protective Equipment (PPE) for personnel performing their duties
- Provide advice about legal authority to monitor supply chains and respond to shortages and potential shortages and related sensitive disclosure issues
- Support intra- and extramural regulatory science research to foster the development and adoption of advanced manufacturing technologies to help prevent and mitigate potential product shortages to better meet the demands of pandemic or emergency response

#### Enforcement Work on Counterfeit or Misbranded Products (\$2.2 million)

- Conduct health fraud related activities including the purchase of undercover/anonymous browser software and health fraud laptops (off FDA network), sample purchasing, and laboratory analysis
- Provide support for the issuance of import screening associated with products and manufacturers affected by impacts of coronavirus on FDA operations and inspections
- Develop outreach materials including education to the public and state partners on impacts of coronavirus
- Provide maintenance for the Animal Drug and Manufacturing System that is being developed with the first supplemental funding to address potential drug shortages by expediting information retrieval to quickly identify and address critical facilities and animal drugs impacted by emerging diseases or natural disasters
- Review FDA Warning (notifies regulated industry about violations) and Untitled (initial correspondence with regulated industry) Letters for legal sufficiency
- Provide legal support to FDA and the US Department of Justice on all proposed enforcement actions
- Litigate seizures, injunctions and criminal prosecutions. Review all press releases/social media related to counterfeit or misbranded products.

#### Work on Emergency Use Authorizations (\$4.8 million)

- Continue work on Emergency Use Authorizations (EUAs) from the first supplemental including operating costs for enhancing standards development to support EUAs,

increase infrastructure storage and computing power capabilities, and the review and legal advice on all proposed EUAs related to coronavirus preparedness and response.

- Actively interact with firms and other entities for more than 200 additional potential EUAs currently under consideration, with more requests coming in every day.
- Work closely with other federal and international government agencies, and non-governmental organizations, e.g., the Centers for Disease Control and Prevention, the World Health Organization, and medical device firms that plan to submit EUA requests for medical countermeasures.
- Provide regulatory flexibility for emergency use of important medical products including drugs, vaccines, and devices as necessary to support the response to COVID-19 as well as legal advice on whether such medical products are covered countermeasures under the PREP Act.
- Provide scientific and technical evaluation of data and regulatory/policy/legal activities.
- Work with HHS Office of General Council to obtain necessary Secretarial determinations and declarations.

#### Pre and Post Market Work on Counter Measures, Therapies, and Vaccines (\$30.0 million)

- Continue working with industry stakeholders to support the vaccine development process
- Continue activities from the first supplemental in addition to the following new activities for the third supplemental:
  - Develop rapid and accurate tests that can be used in a quality control setting for the effectiveness of PPE, particularly gowns and other barriers
- Support non-salary related expenses for recall audit checks, pre-approval inspections, medical counter measures, import screenings, and entry review, including domestic/foreign travel costs, supplies for laboratory analysis, sample purchasing, equipment purchases, and PPE.
- Provide legal advice on investigational products, clinical trials, export, and enforcement discretion.
- Provide legal advice on associated PREP Act issues.

#### Operational Costs (\$4.6 million)

- Supports increased agency costs resulting from the COVID-19 outbreak associated with expanded telework, facilities cleaning and decontamination, and temporary repatriations.

## INDIAN HEALTH SERVICE

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

Activity	Amount
Allocation to IHS, Tribal, and Urban Indian Health Programs	600.000
Electronic Health Record	65.000
Allocated at Discretion of the IHS Director	367.000
<b>Total, IHS Coronavirus Funding</b>	<b>1,032.000</b>

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Preparedness and Response Supplemental Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$1.032 billion included for the Indian Health Service (IHS) in the Coronavirus Aid, Relief, and Economic Security Act.

#### **Planned Activities**

##### Allocation to IHS, Tribal, and Urban Indian Health Programs (\$600 million) –

- IHS Federal Health Programs
  - Allocations to IHS Area Offices and IHS service units for COVID-19 response activities.
- Tribal Health Programs
  - Supplements to Indian Self-Determination and Education Assistance Act (ISDEAA) Title I and Title V contracts and compacts for COVID-19 response activities.
- Urban Indian Health Programs
  - Supplements to existing FAR contracts for COVID-19 response activities.

##### Electronic Health Record (\$65 million) –

- Project management operations, acquisition planning, tribal consultation, Resource and Patient Management System stabilization and support, and initial testing and capacity building.
  - Funds will support IHS Office of Information Technology activities, and may also be obligated through contracts.

##### Remaining Amount to be Allocated at Discretion of the IHS Director (\$367 million) –

- Activities to be determined. Could include: Community Health Representatives, Tribal Epidemiology Centers, telehealth and facilities needs that are critical for COVID-19 response.
  - Funds could be obligated using cooperative agreements, contracts, or existing funding mechanisms.

## CENTERS FOR DISEASE CONTROL AND PREVENTION/ AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

(Dollars in millions)

Activity	Amount
CDC COVID-19 Response and Preparedness	
<i>Domestic Cooperative Agreements to States, Territories, Locals, and Tribes</i>	1,500.000
<i>Public Health Response and Preparedness</i>	1,500.000
<i>Public Health Data Surveillance and Analytical Infrastructure</i>	500.000
<i>Global Disease Detection and Emergency Response</i>	500.000
<i>Infectious Diseases Rapid Response Fund (IDRRRF) <sup>1</sup></i>	300.000
<b>Total, CDC Coronavirus Funding</b>	<b>4,300.000</b>

Activity	Amount
ATSDR COVID-19 Response and Preparedness	
<i>Geospatial Research, Analysis and Services Program</i>	7.500
<i>Pediatric Environmental Health Specialty Units</i>	5.000
<b>Total, ATSDR Coronavirus Funding</b>	<b>12.500</b>

<sup>1</sup>Deposit into the IDRRRF; CDC has no plans to use these funds at this time.

Cases of novel coronavirus (COVID-19) have been detected in most countries worldwide. On March 11, the COVID-19 outbreak was characterized as a pandemic by the World Health Organization. This is the first pandemic known to be caused by the emergence of a new coronavirus. Currently, areas of the United States are seeing different levels of COVID-19 activity and CDC expects widespread transmission of COVID-19 in the United States. In the coming months, most of the U.S. population will be exposed to this virus. All 50 states have reported cases of COVID-19 and 27 states are reporting some community spread of COVID-19. There is much more to learn about the transmissibility, severity, and other features associated with COVID-19 and investigations are ongoing.

The continued support for expansion of critical public health activities – including epidemiology, surveillance, laboratory capacity, infection control, community interventions, communications, and other preparedness and response activities – are essential to meet the needs in this quickly evolving response. In addition to support for state, local, tribal, and territorial jurisdictions, this funding will also support CDC operations, including deployment of field staff and surge support. As the situation continues to evolve, CDC will update the spend plan as necessary.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Preparedness and Response Supplemental Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$4.3 billion included for CDC in the Coronavirus Aid, Relief, and Economic Security Act.

## **Planned Activities**

### **Domestic Cooperative Agreements to States, Territories, Locals, and Tribes** (\$1.5 billion) –

- Through additional grants to state, local, tribal and territorial jurisdictions, CDC will continue to support core public health response activities, including epidemiology, surveillance, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities:
  - CDC has awarded \$631 million to 64 jurisdictions through the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases cooperative agreement, allocating 100% of the fiscal year (FY) 2019 Public Health Emergency Preparedness award to current recipients, as directed by Congress. Funds from this award are available for a variety of activities including, but not limited to, case identification, contact tracing, surveillance, testing capacity, management of COVID-19 in high risk settings, and management and monitoring of healthcare system capacity. This link provides a jurisdiction funding table.
  - CDC plans to provide at least \$125 million to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes. Details are under development.
  - Remaining funds will be distributed through multiple awards through existing mechanisms. Details are under development.

Note: Working Capital Fund and program support costs will be supported through the sections below; all \$1.5 billion will be allocated via grants.

### **Public Health Response and Preparedness** (\$1.5 billion) –

Through contracts, grants, and other mechanisms (e.g., salary and benefits, travel, equipment, supplies, telecommunications, etc.), CDC will:

- Further increase its technical assistance for nationwide efforts for epidemiology and surveillance, laboratory capacity, and infection control. This includes technical assistance for state and local efforts around contact tracing and case investigation in jurisdictions to rapidly respond to COVID-19 cases and strengthening reporting capabilities and availability of real-time data and specimens.
- Accelerate the implementation and subsequent evaluation of effective infection control measures across the continuum of care.
- Expand dissemination of guidance to educate communities about non-pharmaceutical interventions (NPIs) that help slow the spread of illness, like COVID-19.
- Continue to develop and disseminate critical guidance (e.g., health care worker guidance, appropriate care and infection control for patients with COVID-19; Businesses and Employers to Plan and Respond to Coronavirus Disease 2019 (COVID-19); implementation of mitigation strategies for communities with local COVID-19 transmission).
- Continue to develop tools and strategies, provide technical assistance and program support, as well as ensure ongoing communication and coordination among federal, state, local, tribal, and territorial public health agencies and partners throughout the response.
- Support operations, including deploying CDC emergency response field staff to address response needs. CDC will also continue to support operational readiness,

- response, recovery, and preparation for any future respiratory outbreaks with state and local public health and key partners.
- Continue to expand health communications for dissemination of up-to-date information in multiple languages to reach the public and targeted audiences with messaging for all aspects of preparedness and response.
  - Increase work with federal, state, international, and partners to ensure proper protocols are supported to identify, track, and implement appropriate public health actions according to current travel guidance. CDC will also support state and local capacity to assure compliance with all necessary active monitoring requirements.

Note: Working Capital Fund and program support costs will be spread across relevant activities.

#### Public Health Data Surveillance and Analytical Infrastructure (\$500 million) –

Through contracts, grants, and other mechanisms (e.g., salary and benefits, travel, equipment, supplies, telecommunications, etc.), CDC will:

- Leverage data for surveillance, detection, and improving state and local jurisdictions' situational awareness, which will allow for localized and targeted responses and decision-making using more real-time data.
- Expand the electronic exchange and integration of information between public health and health care, including electronic health records, which is essential for timely, accurate, and accessible disease surveillance.
- Support for public health's data science, informatics, and IT workforce; expanding core data, informatics, and IT capacity; advancing interoperable systems and tools; strengthening and expanding collaboration with non-governmental organizations.

Note: Working Capital Fund and program support costs will be spread across relevant activities.

#### Global Disease Detection and Emergency Response (\$500 million) –

Through contracts, grants, and other mechanisms (e.g., salary and benefits, travel, equipment, supplies, telecommunications, etc.), CDC will:

- Expand work with Ministries of Health and international organizations to support country and regional efforts to mitigate the impacts of COVID-19. CDC will support additional cross-cutting partnerships and capacity building work to support vulnerable areas.
- Leverage regional platforms to provide nimble response and extend health security best practices across the agency's global health portfolio.
- Increase CDC's global reach and ability to quickly deploy where needed through a network of pre-existing relationships and planning frameworks.
- Expand CDC's work on the ground side-by-side with public health professionals to increase capacity in the core public health capabilities to detect and control emerging health threats.
- Examples of the types of activities CDC will support include, but are not limited to: providing support and technical assistance to Ministries of Health and international organizations to support country and regional efforts to respond to coronavirus, assisting countries with identifying and isolating patients with confirmed or suspected cases, providing increased support for diagnostics, and expanding the capacity to sequence viruses around the world and ensure the timely sharing of virologic data for vaccine decisions and public health policy recommendations.



Note: Working Capital Fund and program support costs will be spread across relevant activities.

Infectious Diseases Rapid Response Fund (\$300 million) –

- This funding would be deposited in the IDRRRF. At this time, CDC has no plans to use these funds.

Agency for Toxic Substances and Disease Registry (\$12.5 million) –

Through contracts, grants, and other mechanisms (e.g., salary and benefits, travel, equipment, supplies, telecommunications, etc.), CDC will:

- Provide funding for necessary expenses of the Geospatial Research, Analysis and Services Program (GRASP) to support spatial analysis and Geographic Information System mapping of infectious disease hot spots, including cruise ships.
- Provide funding for necessary expenses for awards to Pediatric Environmental Health Specialty Units and state health departments to provide guidance and outreach on safe practices for disinfection for home, school, and daycare facilities.

Note: Working Capital Fund and program support costs will be spread across relevant activities.

# NATIONAL INSTITUTES OF HEALTH

## Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

Activity	Amount
Basic, Pathogenesis, Animal Models, Epidemiology, Surveillance, Natural History	150.000
Diagnostics	30.000
Therapeutics	188.000
Vaccines	115.000
Buildings and Facilities	223.000
<b>Subtotal, NIAID Coronavirus Funding</b>	<b>706.000</b>
<b>NHLBI Coronavirus Funding</b>	<b>103.400</b>
<b>NIBIB Coronavirus Funding</b>	<b>60.000</b>
<b>NLM Coronavirus Funding</b>	<b>10.000</b>
<b>NCATS Coronavirus Funding</b>	<b>36.000</b>
Common Fund High Risk/High Reward COVID19-Related	30.000
<b>Subtotal, Office of the Director Coronavirus Funding</b>	<b>30.000</b>
<b>Total, NIH Coronavirus Funding</b>	<b>945.400</b>

The National Institutes of Health (NIH) will respond to the COVID-19 outbreak by expanding research efforts to accelerate the development of interventions that could help control current and future outbreaks of COVID-19 as well as other coronaviruses with pandemic potential. As with the prior supplemental, the National Institute of Allergy and Infectious Diseases (NIAID) is the lead institute for the NIH effort. NIH has also received funding for additional institutes and centers to contribute to the overall effort by taking advantage of their unique expertise and research resources.

- NIAID will further accelerate and broaden its research activities in response to the pandemic. It will also fund two construction projects to better prepare for future outbreaks of Coronavirus and other infectious diseases: the expansion of the Vaccine Research Center in Bethesda and the replacement of the existing aged and debilitated vivarium at NIAID’s Rocky Mountain Laboratory.
- The National Heart, Lung, and Blood Institute (NHLBI) will study host response and the cardiac, vascular, pulmonary, and hematologic dimensions of COVID-19, and leverage its national networks and clinical trial infrastructure to conduct randomized-control trials in COVID-19 patients and launch a National COVID-19 Longitudinal Study.
- The National Institute of Biomedical Imaging and Bioengineering (NIBIB) will accelerate the development of technologies to address COVID-19 by utilizing its Point of Care Technology Research Network as well as funding relevant projects in a range of areas such as robotics and artificial intelligence.
- The National Center for Advancing Translational Sciences (NCATS) will address common translational roadblocks in order to accelerate the development and deployment of therapeutics for COVID-19, using resources such as its drug repurposing programs/databases and its Clinical and Translational Science Awards (CTSA) program.

- The NIH Common Fund will support high impact research throughout NIH on COVID-19, through its High Risk/High Reward program. This may include basic science, novel diagnostic, therapeutic, and containment strategies, or other innovative ideas.
- The National Library of Medicine (NLM) will address needs for COVID-19 information, including accelerating access to literature and molecular data resources, high quality clinical data for research and care, and new search capabilities.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Aid, Relief, and Economic Security Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$945.4 million included for NIH in the Coronavirus Aid, Relief, and Economic Security Act.

# NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

## Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

(Dollars in millions)

Activity	Amount
Basic, Pathogenesis, Animal Models, Epidemiology, Surveillance, Natural History	150.000
Diagnostics	30.000
Therapeutics	188.000
Vaccines	115.000
Buildings and Facilities	223.000
<b>Total, NIAID Coronavirus Funding</b>	<b>706.000</b>

NIAID's funding builds on the prior supplemental by taking additional measures to aggressively accelerate and broaden research activities to help mediate and contain the pandemic, expedite the development of medical interventions and build a foundation that can be used to prepare for the next Coronavirus outbreak.

This plan describes planned activities for a total of \$706 million included for NIAID in the Coronavirus Aid, Relief, and Economic Security Act.

### **Planned Activities**

**Basic, Pathogenesis, Animal Models, Epidemiology, Surveillance, Natural History (\$150 million)** to accelerate the understanding of and the prevalence of COVID-19, its transmission and natural history of infection.

- Observational cohort and sero-surveillance studies leveraging existing research networks, *e.g.*, the INSIGHT network. Studies, intended to enroll over 10,000 subjects, are intended to delineate the natural history of COVID-19 infection to allow NIAID to accurately power clinical trials; identify predictors of disease progression; determine host factors modifying disease course and monitor the response to different treatments.
- Conduct a surveillance study with the aim of determining the prevalence of SARS-CoV2 infection over time in children and their household contacts and to evaluate the role of children in disease spread. Study will enroll and prospectively observe eligible children that are current participants in existing NIAID pediatric research studies, and their family members. The enrollment goal is approximately 2,000 families.
- Support sero-surveillance studies to understand the prevalence of disease in the United States over time in 10,000 patients, which would complement other research studies by leveraging existing NIH research networks such as NHLBI's Recipient Epidemiology and Donor Evaluation Study (REDS) network and NIAID's Centers of Excellence for Influenza Research and Surveillance (CEIRS) network.

- Address scientific gaps through extramural and intramural research. This would be accomplished through competitive grant supplements, increases to contracts that support research resources (*e.g.*, BEI Resources Repository) provided free to extramural researchers and support of intramural activities. Funds will also support multi-year grant awards made to extramural investigators in response to emergency funding announcements.
- Support a prospective cohort study of 1,000 patients to assess longitudinal immune responses in hospitalized patients with COVID-19. This study is critical for identifying and prioritizing host-directed interventions to limit or mitigate disease progression.

**Diagnostics (\$30 million)** to improve U.S. Government diagnostics development and deployment for future outbreaks.

- NIH's overall role is to support extramural and intramural researchers in developing sensitive, specific, and rapid diagnostic assays and reagents for use in the clinic and laboratory for COVID-19. NIAID's role will also include accelerating the development of multiplex diagnostics to identify COVID-19 and other related coronaviruses. NIAID also plans to provide bridge capacity for diagnostic testing for COVID-19 in CLIA-certified labs at sites within NIAID's existing clinical trials networks.

**Therapeutics and Treatment of Disease (\$188 million)**

- Expand the evaluation of promising therapeutic candidates, including through Preclinical Services support, which pays for the preclinical evaluation (*e.g.*, testing in animals) and product development (*e.g.*, product formulation) of candidates submitted by the extramural community. Funds would also support additional awards in response to the emergency Funding Opportunity Announcement (FOA) and investigator-initiated research.
- Funding would accelerate the following:
  - Conduct our Division of Clinical Research randomized clinical trial of Remdesivir in patients in the early disease stage. It is necessary to do this in a separate trial in order to not delay the results of the ongoing Remdesivir trial.
  - Allow flexibility to conduct 1-2 more Phase 2/2b clinical trials.
- Conduct clinical trials to evaluate immune modulators (*e.g.*, tocilizumab, inhaled immunostimulators, anti-complement, anti-CD-14) for treatment of COVID-19 patients, leveraging the NHLBI Intensive Care Network.
- Explore/develop more candidates through investigator-initiated awards, awards in response to the emergency Funding Opportunity Announcement (FOA), and intramural researchers.
- Conduct a placebo-controlled clinical trial of intravenous hyperimmune immunoglobulin (IVIG) in patients with COVID-19 to determine whether, when added to standard of care (SOC) treatment, administration of IVIG is superior to placebo in terms of reducing disease severity and duration (1000 subjects).

### **Vaccines (\$115 million)**

- Conduct 1-2 Phase2/2b clinical trials of promising vaccine candidates.
- Basic research and prototype manufacturing of components for a universal Coronavirus vaccine.
- Explore/develop additional candidates through investigator-initiated awards, awards in response to the emergency Funding Opportunity Announcement (FOA), and intramural researchers.
- Expand research at the Vaccine Research Center to develop antibodies.

### **Buildings and Facilities (\$223 million)**

- \$165 million for construction to expand the Vaccine Research Center's research facility in Bethesda. Building 40A will be a six-story, 158,000 gross square foot addition to Building 40 that will house BSL-2 laboratories, laboratory support space, administrative support space, and meeting rooms. The ratio will be 61% laboratory space to 39% administrative/meeting room space. Building 40 occupancy is currently 35% - 45% over what was designed, which stresses personnel workflow and VRC infrastructure. This situation is potentially compromising laboratory safety and constricting the VRC's ability to recruit and retain mission-critical expertise to create new programs. Additional space is urgently needed to alleviate overcrowding and to help accelerate development, manufacturing, and clinical study of vaccines and biologics against pandemic health threats. This building will more than double available laboratory space of the VRC, and it will provide collaborative space for a "Center for Pandemic Preparedness," anchored by the VRC, to accelerate discovery and spin-off of successful products to commercial partners. The construction contract is planned to be awarded in FY 2021. It is estimated to take two years to construct and an additional 5-6 months for activation and move-in.
- \$58 million will fund the replacement of the existing aged and debilitated vivarium under current use at NIAID's Rocky Mountain Laboratory. The new building will be a three-story vivarium facility, plus interstitial and mechanical support spaces, totaling 120,000 gross square feet and factoring out as 93% vivarium space and 7% administrative support space. It will contain 35 holding rooms, 28 procedure rooms, and 24 specialty rooms along with autoclaves and cage wash rooms. This new vivarium facility will provide important program support including all Biosafety Level 2 (BSL-2) breeding, holding and experimental programs, as well as quarantine for animals destined for BSL-3 and BSL-4 studies in laboratories at RML. The new facility will provide expanded capabilities for studies with exotic species (like bats) along with special imaging equipment, histopathology, and a multi-vector insectary.

# NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

## Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
COVID-19 Host Targeting Therapies through Clinical and Translational Research	103.400
<b>Total, NHLBI Coronavirus Funding</b>	<b>103.400</b>

Given the major impact of underlying cardiovascular, pulmonary, and hematologic conditions on morbidity and mortality among patients with Coronavirus Disease 2019 (COVID-19), NHLBI is planning a multi-pronged research strategy that leverages its key assets: (1) a **Preclinical Translational Research Platform** to accelerate our understanding of key determinants of host response and the cardiac, vascular, pulmonary, and hematologic dimensions of COVID-19 and develop model systems to rapidly test and advance the development of innovative therapeutics; (2) leverage and expand an existing national **COVID-19 Clinical Trial and Network Platform** and other clinical trial infrastructure ideally suited to execute randomized-control trials in COVID-19 patients with host-directed interventions using repurposed or novel agents aimed at ameliorating tissue injury/reparative responses in the lung, heart, vasculature, and hematologic systems; (3) build on a national networks and clinical infrastructure spanning ambulatory care clinic emergency department, in-patient and intensive care settings with well-phenotyped COVID-19 patients to launch a **National COVID-19 Longitudinal Study with Data Resource and Biospecimen Repository** using a digital data platform and existing data feeds to get comprehensive data to better define the natural history of the disease, identify predictive biomarkers, immunophenotypes, new therapeutic targets, enable patient stratification, and enhance clinical management. This effort will also leverage extensive platforms such as the Recipient Epidemiologic and Donor Surveillance (REDS) Program in order to advance safety of the US blood supply, accuracy of donor sero-surveillance, and rapid development of potential blood-derived therapeutics.

This plan describes planned activities for a total of \$103.4 million included for the National Heart, Lung, and Blood Institute in the Coronavirus Aid, Relief, and Economic Security Act.

### Planned Activities

#### COVID-19 Translational Research Platform: Understanding host responses and the cardiac, vascular, pulmonary, and hematologic dimensions of Coronavirus Disease 2019 (COVID-19) and advancing the rapid development of innovative therapeutics

- Issue research solicitations highlighting the urgent need for research on COVID-19 and on the biological effects of its causative agent, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The supported research will inform efforts to prevent, treat, and/or mitigate this viral infection and its effects on patient heart, lung, and blood function and overall clinical outcome.
  - **Funding Mechanism(s) and recipients:** Research Project Grants, R&D Contracts, and other Research mechanisms to support investigators and institutions poised and able to carry out rapidly carry out translational discovery research - inclusive of early, preclinical and clinical research - to

elucidate key determinants of host responses and the mechanisms underlying the cardiac, vascular, pulmonary, and hematologic dimensions of COVID-19 and to advance development of innovative therapeutics.

### **COVID-19 Clinical Trial and Network Platform: Interventional Randomized Controlled Clinical Trials in COVID-19 Patients**

- Leverage NHLBI's national network of intensive care and emergency department clinical experts, as well as other relevant clinical trial networks and infrastructure, to conduct randomized controlled clinical trials in COVID-19 patients to evaluate treatments aimed at ameliorating the tissue injury/repair responses in the lung, heart, and vasculature and improving clinical outcomes. Interventions currently under consideration include, for example but not limited to: virus-directed agents and host-directed therapies known to have immunomodulatory and anti-inflammatory effects, and viral pathway directed agents. Final selection of the treatments to be tested and trial design will be collaboratively determined through consultations with experts in the field both within and outside the NHLBI-supported networks and in close collaboration as appropriate with FDA, NIAID, BARDA and others.
  - **Funding Mechanism(s) and recipients:** Research Project Grants, R&D Contracts, and other Research mechanisms to support investigators and institutions poised and able to carry these critical clinical studies.

### **The National COVID-19 Longitudinal Study, Patient Registry, Data Resource, and Biorepository: Understanding COVID-19 clinical trajectories, identifying predictive biomarkers, enabling patient stratification, and enhancing clinical management**

- Conduct a largely prospective (but potentially retrospective from existing U.S. cases) study of COVID-19 patients from outpatient/ED presentation to long term outcome and to create a national COVID-19 Patient Registry Data Resource and Biorepository. The study will include targeted collection of patient biospecimens as well as clinical, laboratory, and imaging data for the purpose of: understanding key determinants of the host response; mechanisms underlying associated heart, lung, and blood pathophysiology; providing a multi-omic platform for identification of predictive biomarkers to aid in patient stratification and future case management; and refining novel clinical endpoints for therapeutic trials or intervention strategies. The study will also include a comparative analysis of ARDS patients with COVID-19 to understand disease heterogeneity.
  - **Funding Mechanism(s) and recipients:** Research Project Grants, R&D Contracts, and other Research mechanisms to support investigators and institutions poised and able to rapidly launch and sustain these critical studies.



# NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

## Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Develop Technologies to Address COVID-19	60.000
<b>Total, NIBIB Coronavirus Funding</b>	<b>60.000</b>

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is addressing the urgent need for accelerating the development, translation, and commercialization of technologies to address Coronavirus Disease 2019 (COVID-19). NIBIB plans to support further development of late-stage technologies and solutions that can help overcome the current crisis and set us on a path to health for both the short and long term. All activities described below will be in accordance with the Congressional intent of the funds “to prevent, prepare for, and respond to coronavirus, domestically or internationally.”

This plan describes planned activities for a total of \$60 million included for the National Institute of Biomedical Imaging and Bioengineering in the Coronavirus Aid, Relief, and Economic Security Act.

### **Planned Activities**

#### **Point-of-Care Testing, Sensing, and Imaging**

Mechanisms used in this research area include supplemental funding and competitive revisions to existing NIBIB grantees, new investigator-initiated research project grants, and other transaction authority

The US COVID-19 death rate is currently growing exponentially and there is a substantial unidentified pool of infected individuals. In order to maximize mitigation efforts and save lives, there is an urgent need to develop coordinated public health strategies based on substantially expanded COVID-19 testing and population monitoring at the point of care and home.

NIBIB can mobilize its proven Point of Care Technology Research Network (POCTRN) to innovate rapid, scalable testing for COVID-19 to prevent infection, screen large populations, remotely monitor disease onset and recovery, and triage patients in emergency settings. Rapidly deployable examples may include:

- Ultrasensitive molecular and viral diagnostics that can enable home-based testing.
- Wearable sensors to remotely monitor body temperature, blood oxygenation, and coughing. Widely deployed, these can monitor healthy individuals prophylactically and follow recovery of those infected. Remote monitoring can reduce interactions with infected individuals and thus decrease the spread of COVID-19. These platforms can be integrated with artificial intelligence/machine learning to continuously monitor for worsening conditions and raise alerts for medical care providers.
- Non-contact mass fever screening and vital sign assessment in areas such as public transportation hubs and security checkpoints by remote-sensing and imaging methods.

These could also be adapted for use in various settings such as the clinic, workplace, and home, and integrated with cellphone-based platforms.

- Imaging technologies that can be delivered rapidly at the point-of-care (POC) such as the bedside to assess the extent of lung and other organ infection/function.

### **Artificial Intelligence Algorithms and Computational Technologies**

Mechanisms used in this research area include supplemental funding and competitive revisions to existing NIBIB grantees, new investigator-initiated research project grants, and other transaction authority.

The medical community has been slowly moving toward integrating digital personal health into conventional medicine for several years. Progress has been slow due, in part, to the difficulty of getting consensus around “use cases” and value propositions. The COVID-19 crisis is a compelling use case that can spur new capabilities and demonstrate the potential of digital health to benefit all areas of medicine.

NIBIB can coordinate the development of a digital health platform to modernize the management of COVID-19 as an exemplar for the broader healthcare enterprise. This effort is envisioned as a coalition of multiple sectors that are poised to contribute to a solution: federal agencies, the technology industry, and the NIH medical and bioengineering research communities.

A proposed digital health platform would integrate health data from COVID-19 tests, health status sensors, and electronic medical records into a “mobile app” that could be made available to the entire population through smart phones. Information derived from the app could inform personal health care decisions, public policy, and clinical trials in real time. For example:

- Health care providers can monitor data remotely to evaluate patients at home and intervene if conditions deteriorate, streamlining the use of healthcare resources.
- De-identified data from individuals can be tagged with location services to automate contact tracing. This can inform public health decisions, pinpointing the need for local mitigation strategies.
- Potential clinical trials of therapies for COVID-19 could be possible using a large population of connected individuals who could be monitored while generating continuous information and feedback on therapeutic response. This would dramatically accelerate the development and validation of new therapies and cures.
- CT/X-ray imaging has been a key tool to reveal early signs of lung infection, provide help in making clinical decisions, and optimize healthcare resources. With high volumes of COVID-19 patients, fast and accurate image interpretation is essential for saving lives. NIBIB could lead an effort to accelerate the development of validated artificial intelligence (AI) image algorithms for rapid characterization of lung infection, differential diagnosis, prognosis, and response to therapy. Image data could also be evaluated in combination with viral tests, vital signs, etc. and be included in the digital health platform for longitudinal patient monitoring.

The NIBIB can support development of innovative healthcare solutions that will be necessary components of a comprehensive digital health platform. Realizing the potential of such a platform to rapidly address the COVID-19 pandemic requires substantive partnerships with industry for scale up and dissemination. Innovations from small business will also need to plug into the apps produced by “Big Tech”. NIBIB supports an array of small bioengineering startups around the country ready to contribute to an app business ecosystem oriented to personal and population health. NIBIB can harness bioengineering innovation, engage the big and small tech sectors, and coordinate this effort through partnership with the Foundation for NIH. This concerted engagement can bring NIH innovations to commercialization quickly to address the COVID-19 crisis.

### **Medical Devices, Therapies and Cures**

Mechanisms used in this research area include supplemental funding and competitive revisions to existing NIBIB grantees, new investigator-initiated research project grants, and other transaction authority.

This research program will develop medical devices to optimize COVID-19 therapy, recovery, and caregiver safety. This program will take advantage of ongoing technology development efforts for infectious disease, for example:

- Further the development of robots and robotic technologies, e.g. the robotic nurse, into patient care for COVID-19 (developed previously for Ebola and other highly infectious diseases). This will reduce the workload and exposure of human health care workers, allowing them to provide a higher level of care than was possible in recent outbreaks.
- Develop devices with integrated sensors that allow successful intubation by untrained/minimally trained health workers. This can reduce bottlenecks in dealing with large numbers of patients that may need to be placed on ventilators.

### **Engineered Biological Systems**

Mechanisms used in this research area include supplemental funding and competitive revisions to existing NIBIB grantees and new investigator-initiated research project grants.

As a complement to vaccine research, NIBIB supports the engineering of novel cell-based technologies for detecting and eradicating infected cells. An example of this synthetic biology approach is genetic manipulation of the immune system to detect the virus and trigger a therapeutic response. Signaling pathways in T cells may be engineered to actively detect SARS-Cov-2 infection in vivo and produce peptide therapeutics to specifically neutralize the virus.

NIBIB develops micro-physiologic organ simulator platforms (‘tissue chips’) for high-throughput drug screening and to assess new drugs for entry into clinical trials. In this program, NIBIB can spur development of organ simulator platforms for lung and immune system that will speed the identification and testing of new drug therapies for COVID-19.

# NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

## Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

(Dollars in millions)

Activity	Amount
Therapeutics	36.000
<b>Total, NCATS Coronavirus Funding</b>	<b>36.000</b>

This plan describes planned activities for a total of \$36 million included for NCATS in the Coronavirus Aid, Relief, and Economic Security Act.

### Planned Activities

The NIH's National Center for Advancing Translational Sciences (NCATS) is focused on applying innovative strategies and technologies to accelerate *translation*, the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public. NCATS has developed multiple programs to overcome common translational roadblocks that will be applied to accelerate the development and deployment of therapeutics for the Coronavirus pandemic.

### Specific Activities:

#### NCATS programs to accelerate Coronavirus therapeutics development (\$36 million) –

Before a treatment for Coronavirus can be given to a person, therapeutic candidates must be identified and undergo substantial preclinical development and testing for safety and effectiveness. NCATS' large and unique compound collections and high throughput screening capabilities will be used to rapidly identify potential candidates that alter Coronavirus activity and infection. Human tissue models will be used to evaluate physiological responses to potential Coronavirus therapeutics. Promising compounds will then be rapidly advanced to the stages of characterization and testing required by the FDA for first-in-human clinical trials. In addition, drugs already approved by FDA for other conditions can be repurposed for Coronavirus, and NCATS will leverage its several longstanding repurposing programs and databases to identify new uses for these drugs that can be rapidly advanced to early clinical trials for Coronavirus.

The NCATS Clinical and Translational Science Awards (CTSA) program, including its Trial Innovation Network (TIN) and Clinical Data to Health (CD2H) activities, provides a unique nationwide network of academic institutions conducting clinical translational research that will be leveraged for the Coronavirus pandemic. The use of individual CTSA-supported core resources (e.g., advanced scientific instruments, highly-specialized facilities, and regulatory expertise) and the TIN will assist in the rapid deployment and surge capacity for research and clinical trials on Coronavirus and advance the translation of research findings into therapeutics, including drugs and vaccines. The CTSA CD2H and NCATS Translator programs will utilize informatics resources to facilitate identification, staging, and stratification of Coronavirus cases and responses to treatment across the United States.

## NIH/OFFICE OF THE DIRECTOR/COMMON FUND

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Common Fund High Risk/High Reward COVID19-Related	30.000
<b>Total, NIH/OD/Common Fund Coronavirus Funding</b>	<b>30.000</b>

This plan describes planned activities for a total of \$30 million included for NIH/OD/Common Fund in the Coronavirus Aid, Relief, and Economic Security Act.

#### **Planned Activities**

##### Common Fund High Risk/High Reward COVID19-Related Research (\$30 million) –

- The Common Fund High Risk/High Reward program supports innovative research that is expected to have exceptional impact. It allows creative scientists to enter new fields of research based only on their ideas for expected impact; preliminary data are not required. The program supports research across the NIH mission; however, the funds provided through the Supplemental Act will be targeted to COVID-19 related research. This may include basic science to understand the SARS CoV2 virus and the COVID19 disease, novel diagnostic strategies, novel therapeutics, public health/pandemic containment strategies, or other innovative ideas. The funds will be issued as a combination of supplements or competitive revisions to existing Research Project Grants within the High Risk/High Reward program in FY20 and to new Research Project Grants beginning in FY21. All projects supported by these funds will be in accordance with the Congressional intent of the funds provided to the Common Fund “to prevent, prepare for, and respond to coronavirus, domestically or internationally” (H.R. 748)

# NATIONAL LIBRARY OF MEDICINE

## Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
COVID-19 Literature and Clinical Data	10.000
<b>Total, NLM Coronavirus Funding</b>	<b>10.000</b>

The National Library of Medicine is the leading research center in computational health and the world's largest biomedical library, housing a 30M+ literature citation repository, an archive of full-text articles and global molecular data banks that house the genomic sequences that aid in surveillance and tracking of virtual outbreaks. The NLM's intramural and extramural programs undertake research developing and applying advanced analytics addressing problems ranging from discerning genomic similarity to computational phenotyping to clinical decision support. We house and disseminate many of the standards that make electronic health records data interoperable.

This plan describes planned activities for a total of \$10 million included for NLM in the Coronavirus Aid, Relief, and Economic Security Act.

### **Planned Activities**

Enhancing access to COVID-19 literature and molecular data resources. This will include ensuring that NLM Collection Materials for COVID-19 are available electronically; developing a PubMed portal for COVID-19 literature collected through text mining; and ensuring rapid sequence submission and access through GenBank and VirusHub.

Improve the quality of clinical data for research and care. This will include implementation guidelines, training for standardization, and addition of codes to support COVID-19-related laboratory tests using the LOINC (Logical Observation Identifiers Names and Codes) standard for the electronic exchange of clinical health information, and development using the VSAC (Value Set Authority Center) repository and authoring tool to enable standardized sharing of COVID-19 terminology updates.

Accelerate Research including deep phenotyping, text-mining real-time surveillance. This will include public health surveillance using virus genomics, health data, and social media data to identify the spread of COVID-19; AI/machine learning, analytics and visualization of image and clinical data to support clinical decisions in real time; and mining clinical data for 'deep phenotyping' models that can be used to identify or predict presence of COVID-19.

## SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

Activity	Amount
Certified Community Behavioral Health Clinics	250.000
Suicide Prevention Programs	50.000
Emergency Response	110.000
Tribal Response	15.000
<b>Total, SAMHSA Coronavirus Funding</b>	<b>425.000</b>

This plan describes planned activities for a total of \$425 million included for SAMHSA in the Coronavirus Aid, Relief, and Economic Security Act.

#### **Planned Activities**

##### Certified Community Behavioral Health Clinics (\$250 million) –

COVID-19 will increase the number of Americans living with mental and/or substance use disorders as the pandemic increases imposes trauma, anxiety, and grief. Funding will be used to increase the number of grantees awarded through the CCBHC Expansion grant program. The purpose of this program is to increase access to, and improve the quality of, community mental and substance use disorder treatment services through the expansion of CCBHCs. CCBHCs provide person- and family-centered integrated services. The CCBHC Expansion grant program must provide access to services including 24/7 crisis intervention services for individuals with serious mental illness (SMI) or substance use disorder (SUD), including opioid use disorders; children and adolescents with serious emotional disturbance (SED); and individuals with co-occurring mental and substance disorders (COD). SAMHSA expects that this program will provide comprehensive 24/7 access to community-based mental and substance use disorder services; treatment of co-occurring disorders; and physical healthcare in one single location. As Americans across the country struggle with increases in depression, anxiety, trauma, and grief due to COVID-19, this program is uniquely positioned to provide immediate and integrated assistance at the community level to those who suffer from SMI, SUD, SED, and COD.

##### Suicide Prevention Programs (\$50 million) –

SAMHSA has seen an 890% surge in call volume to the Disaster Distress Helpline due to the COVID-19 pandemic and a similar increase in calls and texts received by National Suicide Prevention Lifeline. Funding will be used to support expansion of call center capacity to address suicide prevention needs nationwide. Funding will be used to support the expansion of suicide prevention efforts for adults at risk of completing suicide. The lifeline and disaster distress helpline are expected to face an increased strain as the pandemic imposes traumatic experiences across the country. This will be both in the context of community suicide prevention efforts, as well as suicide prevention in the context of healthcare delivery systems. Funding will support states and communities in advancing efforts to prevent suicide and suicide attempts among adults age 25 and older, in order to reduce the overall suicide rate and number of suicides in the U.S. nationally. Addressing suicide prevention among adults is imperative to decreasing the nation's

suicide rate. Funding will also be used to raise awareness of suicide, establish referral processes, and improve care and outcomes for individuals who are at risk for suicide.

Emergency Response (\$110 million) –

SAMHSA recognizes there are currently 57.8 million Americans living with mental and/or substance use disorders (National Survey on Drug Use and Health, 2018). The current national crisis of COVID-19 will certainly contribute to growth in these numbers. Americans across the country will struggle with increases in depression, anxiety, trauma, and grief. There is also anticipated increase in substance misuse as lives are impacted for individuals and families. Funding will be used to support state/territory system development of systems of care to meet the needs of those with substance use disorders and mental disorders. Each state will received up to \$2 million, with territories receiving \$500,000. Funding will be made available for the provision of direct treatment services for those with SUD and SMI. SAMHSA expects states and territories to take the lead on identifying needs, but would expect the funding to support evidence-based treatment for mental and substance use disorders, including individual and family counseling, Cognitive Behavioral Therapies, medication management, recovery coaching, employment coaching, etc.

Tribal Response (\$15 million) –

To quickly provide funding in response to the COVID-19 pandemic, SAMHSA is supplementing all of the current FY 2020 Tribal Behavioral Health (TBH) grants in order to meet the acute needs of tribes. This will allow for the awarding of supplements to 154 current grant recipients to meet the increased mental and substance use disorders of tribes during the COVID-19 pandemic. The purpose of the TBH program is to prevent suicide and substance misuse, reduce the impact of trauma, and promote mental health among American Indian/Alaska Native (AI/AN) youth through the age of 24 years. The program is intended to reduce the impact of mental and substance use disorders, foster culturally responsive models that reduce and respond to the impact of trauma in AI/AN communities<sup>1</sup>, and allow AI/AN communities to facilitate collaboration among agencies to support youth as they transition into adulthood. The funding will foster culturally responsive models that reduce and respond to the impact of SUD and SMI on AI/AN communities and align with current funding practices.



**CENTERS FOR MEDICARE & MEDICAID SERVICES**  
**Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
State Survey Agency Support	100.000
Medicare Administrative Contractor COVID-19 Support	21.700
Technical Assistance Support for States	2.200
Beneficiary Outreach and Education	28.100
Expansion & Surge support for CMS End User IT services	8.000
Nebraska COVID-19 Hotline for Health Professionals and Systems	7.000 - 15.000
Other COVID-19 Activities	7.200
Miscellaneous Travel, Training, Supplies, Overtime	5.000
Contingency	12.800 - 20.800
<b>Total, CMS Coronavirus Funding</b>	<b>200.000</b>

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Preparedness and Response Supplemental Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes currently planned activities for a total of \$200.0 million included for the Centers for Medicare and Medicaid Services (CMS) in the Coronavirus Aid, Relief, and Economic Security Act, PL 116-136. CMS may update non-State Survey Agency funding allocations based on need as the COVID-19 Public Health Emergency evolves.

**Planned Activities**

**State Survey Agency (SSA) Support (\$100.0 million) –**

- The funding will go towards a response to COVID-19 and related activities, which is currently evolving. Generally speaking, the majority of the funding will go to State Survey Agencies (SAs) and contract surveyors to support direct surveys, including expanded surveys, dedicated COVID-19 surveys, enhanced facility surveillance and complaints, with the remaining funds going towards the management of surveyor operations, enhancements in information systems to improve all-hazards tracking capabilities, and training. CMS will award additional funds to SAs via grants and will be based on supplemental needs identified by each SA which should roughly correlate to the impact of the outbreak in the each State. Please see below for more detail regarding the specific workload CMS will be targeting with the funding:
  - Although QSO-20-12-All narrowed the scope of priorities for SAs and suspended non-emergency inspections, CMS anticipates the narrowing will only be for a relatively short time period during the most acute phase of the virus’s spread. CMS expects survey demand to significantly increase in light of the deadliness of COVID-19 in the Long Term Care (LTC) population, as evidenced by the *Life Care Center of Kirkland* experience in Washington, where the virus is associated with numerous deaths. The available funding will support the entirety

of the survey priorities identified in the SA guidance memorandum. CMS will be significantly strengthening its infection control protocol, which will require both additional training and more time to complete on-site.

- CMS expects complaints to increase considerably. In 2019, 40% of nursing homes surveyed had infection control violations, but received no sanctions. In light of this and the threat presented by COVID-19, CMS will be sanctioning far more facilities with those violations. A proposed solution will be a “directed plan of correction” which requires the SA to evaluate the root causes of infection control violations and tailor interventions to fix those problems.
- Even with the additional funding, CMS does not anticipate that it will lift the suspension on non-emergency inspections in the short-term. The COVID-19 crisis is very unstable and there’s a high probability the spread of the outbreak could continue for several more months, which would require sustained survey activity for high priority surveys. However, once expanded or normal survey operations resume, a portion of the available resources will be used to resolve the delayed survey work that will have to be performed, in addition to the expanded focus on infection control concerns.
- This funding will also support Personal Protection Equipment (PPE) and Medical Clearance for CMS Surveyors. CMS will fund additional PPE (N-95 face masks, surgical gowns, goggles, gloves, and thermometers) for CMS surveyors. PPE prevents the transfer of COVID-19 while staff are conducting CMS business at potentially contaminated locations. These purchases will be made via Purchase Card. The funding will also satisfy the Service Level Agreement (SLA) to cover the expedited need for all 107 CMS surveyors to get medical clearance to ensure surveyors are allowed to wear respirator masks. Surveyors must also be re-tested for each new respirator model.

#### Medicare Administrative Contractor (MAC) COVID-19 Support (\$21.7 million) –

- *General MAC Support (\$5.7M)* - This funding will generally support the MACs ability to answer provider calls related to COVID-19, claims processing and data analytics related to COVID-19, and other MAC contingencies. The MACs started receiving an uptick in calls related to COVID-19 when the virus first appeared in Washington State. CMS was able to identify the uptick based off of the questions it knew the MACs were receiving from providers about coding, pricing, and policy/coverage waivers in response to the virus and the subsequent emergency declaration. This funding also supports the development and implementation of a new COVID-19 diagnosis code as well as the data analytics and surveillance of COVID-19 impacts through real-time monitoring of claims data. Additionally, this funding would provide support for other miscellaneous activities the MACs may have to conduct as a result of the COVID-19 pandemic. An example would be that the MACs are working to execute on having their staff—including call-center staff—work at home to comply with the various recommendations associated with preventing the spread of COVID-19.
- *MAC Expedited Provider Enrollment (\$16M)* – This funding will be specific to emergency care and HHA services initially and will eventually expand to other provider types. The funding should expedite provider enrollment timeframes by up to 50%. The

cost would also include licensure requirements that MACs would be responsible for checking outside of their jurisdiction.

Technical Assistance (TA) Support for States (\$2.2 million) –

- The TA Support to States will be provided via contract and will focus on coverage issues, development of 1135 waiver requests, monitoring and evaluation of related flexibilities, eligibility and provider enrollment issues, and other related requests. CMS will provide support for State calls, web content updates, and other communications. CMS will also provide support to prepare 1115 letters and package; the contractor would also push necessary information to Medicaid.gov for posting.

Beneficiary Outreach and Education (\$28.1 million) –

- *1-800-MEDICARE Call Center (\$20.5M)* – A small portion of this funding (approximately \$500,000) will be used to train the workforce at the Call Center to cover additional COVID-19 related calls. This funding will also cover additional calls from Medicare beneficiaries wondering if Coronavirus is covered by Medicare or other Coronavirus related questions. As of March 18<sup>th</sup>, CMS has received approximately 12,000 calls related specifically to COVID-19. This funding will be placed on the existing CMS Call Center contract. The remaining \$20M will be used as a contingency in the event that the call volume increases dramatically. A dramatic rise in the call volume or significant CMS program changes would necessitate the urgent hiring of additional Customer Service Representatives (CSRs), which becomes a costly exercise in call center operations. This contingency will also support costs to transition the call center workforce to a more telework-enabled operation.
- *Medicare Education and Outreach Campaign (\$3.1M)* - This funding will pay for a national digital Medicare focused campaign around COVID-19. The campaign would utilize existing CMS contracts and would provide a targeted set of information that is specifically for people with Medicare. In addition to Medicare specific flexibilities, campaign messaging will be leveraged from cleared CDC information and will be tailored specifically for this high risk target audience.
- *Medicare.gov (\$4.5M)* - In response to the pandemic, CMS will likely delay the rollout of the new Medicare Care Compare tool, keeping the existing Quality Compare tools in place on Medicare.gov longer. This funding will support a 6-month extension of our contract which is currently scheduled to end in August. This funding will support ongoing operations of the existing Quality Compare tools, as well as time sensitive modifications to support the policy changes planned for the Medicare quality reporting programs to address COVID response.
- *Relationships, Events, Contacts, and Outreach Network (RECON)* – The funding will be to support the creation of COVID-19 resource mail boxes for external stakeholders (ex: 1135 box, and Chief Medical Officer Resource box). This funding will also support the purchasing of additional licenses for CMS Regional office and CMS Central Office staff to be able to access feedback and help with the additional volume of questions.

Expansion & Surge Support for CMS End User IT Services (\$8.0 million) –

- This funding will cover current and expected expansion of IT support services provided by key CMS vendors/contractors. The funding will support the majority of the CMS workforce working remotely, allowing CMS to continue its mission during the pandemic. In particular, the services will be used to do the following:
  - Ensure the stability of the Virtual Private Networks (VPN) connectivity;
  - Increase collaboration capability by adding Zoom For Government (FedRamp Certified) as an alternative, and migrating to the cloud-based version of WebEx;
  - Increase support for CMS end users (employees) that need help with their technology (e.g. mobile phones, laptops, video teleconference) by applying funds to the IT Service/Help Desk, including for expanded hours;
  - Purchase additional bandwidth and hardware, including mobile phones, data capacity, and line activations, laptops, and service desk extensions; and,
  - Increasing program management and data analytic support to proactively address IT issues and identify areas for improvement.

Nebraska COVID-19 Hotline for Health Professionals and Systems (NECHOHPS) (\$7.0 million - \$15.0 million)

- NECHOHPS will serve as a national resource to enable optimal healthcare response to the emerging pandemic. This activity will provide direct access to 24/7 resources for technical information related to patient management, infection prevention and control, and health system operations. In addition to web-based resources, NECHOHPS will enable real-time consultation with leading technical experts within these domains to support hospital, health system, and individual healthcare provider response to COVID-19, especially those in rural and under-served regions without established specialty networks. The funding amount for this resource is still under development due to the evolving nature of the pandemic.

Other COVID-19 Activities (\$7.2 million) –

- *Medicare Part C & D Systems* - Funding for changes to Parts C and D systems to accommodate potential payment, data collection, and quality assessment changes. This funding would be placed on existing CMS contracts.
- *Digitizing All Critical Mail (\$2.4M)* - Funding will be used to have a contractor quickly begin digitizing all critical mail for CMS Components and Offices given that the Agency is urging employees to telework for an extended period of time. A significant amount of critical mail (more than 100,000 pieces of mail) has accumulated since the Agency has been without in-person mail service since March 16, 2020. CMS receives approximately 7,500 pieces of mail on a daily basis. CMS is responsible for ensuring that beneficiaries have access to quality care and ensuring that it can make timely payments to providers who provide care to its beneficiaries. Some of the mission critical mail consists of Medicare Enrollment packages that must be timely processed to ensure beneficiaries' healthcare is timely provided, premium payments, beneficiary correspondence that is time-sensitive and can impact their care, executive correspondence that is time sensitive. Digitizing this mail allows for critical CMS work to continue during an extended full-time telework period. CMS employees have already expressed concern that they are unable to complete their workload as they are unable to obtain mail unless they come into work.

- *Automation and COVID-19 Tracking* – This funding will be used to support our Emergency Preparedness and Response Operations (EPRO) team which oversees Continuity of Operations (COOP), Emergency Management, and Disaster Recovery (DR) for CMS. For the pandemic, the team processes internal and external questions, requests, waivers, and other critical information management manually, which is then collated and shared for collaboration across CMS. The funding will be used to rapidly automate some of our COOP and emergency management processes to free up staff and ensure our ability to properly track and share information with all parties on a 24/7 basis. This automation will also provide for enhanced emergency preparedness abilities during both the current pandemic and in future emergency events such as a COOP declaration, hurricanes, wild fires, domestic terrorism, and earthquakes. This funding would utilize a new contractor to complete the work described above.
- *T-MSIS Infrastructure and Analytics* – This funding will be used to do additional runs to produce T-MSIS Analytic Files (TAFs) which would then be used in other analytic reports related to COVID-19. The additional runs of TAFs will require more concurrent space needs, with far more recent data than is typical, to support COVID-19 analytic requests using T-MSIS data. CMS plans use this data to do analysis on telehealth services, hospital admissions from nursing homes, enrollment, and associated expenditures. CMS would utilize existing contracts to complete this work.
- *Regulatory Work* - This funding will be placed on a contract to support Medicare regulatory changes that CMS is putting forth quickly based on the COVID-19 outbreak. These are being posted as Interim Final rules with Comment (IFC). The first IFC was published on March 30, 2020 and the second is currently under development. CMS anticipates there will be many comments on these rules and that CMS will need to pay a contractor to track, triage, and consider all applicable comments on an expedited basis.
- *COVID-19 Inquiry Response Tool (\$2.2M)* – This funding will support the newly created COVID-19 email inquiry response tool which will address external stakeholder inquiries, i.e., providers, suppliers, associations, advocacy groups, and internal staff questions that pertain to Agency operations as well as help CMS track and manage the inquiry inflow and responses. This was originally formed as an email box and SharePoint solution, but the volume of questions the CMS COVID-19 Response team is handling is beyond the capability of that application for the long term. This new approach will reduce the Agency’s cybersecurity risk, allowing CMS to shift away from the use of a resource mailbox as a primary means for receiving inquiries. The costs will be partially offset (estimated \$600,000) in salary and benefit costs, as staff currently performing intake and triage duties will shifted to other Agency work. CMS will be leveraging an existing contract to quickly provide a tool that can handle the volume of inquires CMS is receiving about COVID-19.

Miscellaneous Travel, Training, Supplies, Overtime (\$5.0 million) –

- This funding would support miscellaneous mission-critical travel, training, supplies and/or staff overtime needed to address the needs for COVID-19. Such mission-critical travel is aligned with OMB’s recent travel guidance as outlined in the *Updated Federal Travel Guidance in Response to Coronavirus* agency memo. The funding would also

support various miscellaneous needs related to COVID-19 that represent costs less than \$15,000.

Contingency (\$12.8 million - \$20.8 million) –

- This funding is unallocated and represents a contingency budget in the event that current costs come in higher than anticipated, CMS identifies new needs not identified in the current spend plan, the scope and scale of the COVID-19 changes significantly, and/or CMS is tasked with new work related to COVID-19.

**ADMINISTRATION FOR CHILDREN AND FAMILIES**  
**Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Low Income Home Energy Assistance Program	900.000
Child Care and Development Block Grant	3,500.000
Children and Families Services Program (CFSP)	1,874.000
<i>Community Services Block Grant (non-add)</i>	<i>1,000.000</i>
<i>Head Start (non-add)</i>	<i>750.000</i>
<i>Domestic Violence Hotline (non-add)</i>	<i>2.000</i>
<i>Family Violence Prevention and Services (non-add)</i>	<i>45.000</i>
<i>Runaway and Homeless Youth (non-add)</i>	<i>25.000</i>
<i>Child Welfare Services (non-add)</i>	<i>45.000</i>
<i>Federal Administration (non-add)</i>	<i>7.000</i>
<b>Total, ACF Coronavirus Funding</b>	<b>6,274.000</b>

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Aid, Relief, and Economic Security Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$6,274 million included for Administration for Children and Families in the Coronavirus Aid, Relief, and Economic Security Act.

**Planned Activities**

Low Income Home Energy Assistance Program (\$900 million) –

A total of \$900 million is provided to support LIHEAP, with the expectation that funds will be allocated and distributed to states, tribes, and territories based on the LIHEAP formula used for the FY 2019 awards. While other uses are allowed, ACF anticipates that grantees will use this supplemental funding to provide assistance in managing costs associated with home energy bills, including implementing policies and practices used during energy crises.

Our early preliminary estimates are that approximately:

- \$885 million will be allocated to all states and the District of Columbia;
- \$10.2 million will be allocated to tribes and tribal organizations, with exceptions noted later;
- \$4.5 million (0.05%) will be directed to five territories; and
- \$0 will be allocated for Training and Technical Assistance (T&TA) and monitoring.

LIHEAP supplemental funds will support services and strategies directly related to the consequences of COVID-19 following the normal purposes and rules. Emphasis will be to support immediate community response and recovery needs related to home energy assistance. ACF plans to award supplemental funds in FY 2020. This process design will give LIHEAP

grantees and subgrantees maximum flexibility in deciding when and how to obligate funds through the end of FY 2021 to meet the needs of their communities.

- Congress waived the normal carryover limit for grantees of 10 percent, allowing grantees to reserve their share of these supplemental funds for heating assistance for the winter of 2020/2021. Other normal federal statutory and regulatory requirements remain in place for these funds.
- At the grantee level, the legislation does not waive, or give HHS authority to waive, the administrative cost cap for grantees (10 percent for states/territories and a slightly higher calculation for tribes). The administrative cost cap will likely factor into grantees' decisions about the feasibility to take new applications versus issuing supplemental benefit payments to their existing caseload.
- There are no distinctions in the legislation regarding tribes and tribal organizations. Therefore, ACF assumes that current tribal LIHEAP grantees will receive supplemental funding if they normally receive LIHEAP funding based on Census data or agreements with their states based on a percentage of the state share or an agreed upon household count.
- There is no provision for federal training and technical assistance, administration, or monitoring funding for the supplemental grants.

#### Child Care and Development Block Grant (\$3.5 billion) –

A total of \$3.5 billion is provided for the CCDBG program. These funds will be allocated to state, territory, and tribal Child Care and Development Fund (CCDF) Lead Agencies based on the pre-existing statutory formula from the CCDBG Act that considers the number of children under age five, the number of children qualifying for school lunch programs, and per capita income.

- States, including the District of Columbia and Puerto Rico, will receive \$3.4 billion.
- Territories will receive ½ of one percent (\$17.5 million).
- Tribal Lead Agencies will receive 2.75 percent (\$96.3 million).

As recipients of a block grant, Lead Agencies have discretion to distribute and prioritize CCDF funds to meet their needs. That discretion includes the flexibility to use CCDF funds for child care subsidies to families to pay for child care and/or for grants paid directly to child care providers to help them improve quality and retain supply. Funds will be made available to grantees for allowable CCDF services, including but not limited to:

- Payments and assistance to child care providers in the case of decreased enrollment or closures related to the coronavirus so that they are able to remain open or reopen and continue to pay the salaries and wages of their staff;
- Child care services to health care sector employees, emergency responders, sanitation workers, and other workers deemed essential during the response to the coronavirus by public officials;
- Cleaning and sanitation expenses and other activities necessary to maintain or resume the operation of programs; and
- Mental health consultation.

In addition, \$10.1 million will be used for federal administrative expenses and technical assistance. These activities include:



- Facilitation of rapid child care referrals for essential workers to child care with immediate openings, which includes consultation with subject matter experts, CCDF Lead Agencies, local entities, and stakeholders on how to leverage deployment of emerging business practices during the crisis and in the near future to keep child care providers open and available; and
- Staff and contractor support for the administration, oversight, and reporting of grant awards. Funds may be used to pay salaries of federal employees.

Community Services Block Grant (\$1.0 billion) –

A total of \$1 billion is provided to support the Community Services Block Grant program with the expectation that funds will be allocated and distributed to states, tribes, and territories based on the regular CSBG formula. Of the \$1 billion total supplemental appropriation:

- \$5 million (1/2 of 1 percent of the total appropriation) will be for territories (excluding Puerto Rico);
- \$980 million, will be for states (including Puerto Rico and tribes); and
- \$15 million (1.5 percent of the total appropriation) will be for training and technical assistance and federal administrative expenses. Of this amount, not less than \$7,500,000 will be distributed directly to eligible entities, organizations, or associations as described in the CSBG Act.

CSBG supplemental funds will support immediate community response and recovery needs. ACF plans to release funds in FY 2020. This will allow for local eligible entities to expend funds through the end of FY 2023, if appropriate and necessary, and promote timely obligation and expenditure to support short-, mid-, and long-term response and recovery-related activities. This funding will also support cooperative agreements and/or contracts for training and technical assistance.

Head Start (\$750 million) –

A total of \$750 million is provided to respond to the coronavirus for Head Start programs. This funding will support grants directly to local programs to deliver high-quality summer learning experiences and to respond to other immediate and ongoing consequences of the coronavirus.

- Up to \$500 million will fund a supplemental summer program for existing Head Start grantees that can demonstrate they have the demand for, and capacity to deliver, high-quality summer learning experiences for all or a portion of their preschool enrollment. The priority for this program is to serve all Head Start children entering Kindergarten this year and all children with Individualized Education Plans. Similar to the approach used for the most recent disaster recovery funding, grantees will submit an intent to apply so that ACF can assess grantee interest, ensure there is sufficient funding for these priority children, and determine if additional children can be served. Grantees will then complete an application for a supplemental award to offer a summer program that includes the proposed enrollment, approach, and budget, which will be reviewed by federal staff and awarded on a rolling basis consistent with what the funding can support.
- Of the \$750 million, no less than \$248 million will be made available for all grantees as supplemental grants for various other programmatic activities in response to the

coronavirus. Activities could include mental health services, supports, crisis response, and intervention services; coordination, preparedness, and response efforts with state, local, tribal, and territorial public health departments and other relevant agencies; costs of meals and snacks not reimbursed by USDA; training and professional development for staff on infectious disease management; purchasing necessary supplies and contracted services to sanitize and clean facilities and vehicles; and other costs that are necessary to maintain and resume the operation of programs, such as substitute staff, technology infrastructure, or other emergency assistance.

- Additionally, up to \$2 million will also be used for federal administration to support administration of these grants. Funds may be used to pay salaries of federal employees.

#### Domestic Violence Hotline (\$2 million) –

A total of \$2 million is provided for the purpose of providing domestic violence hotline services remotely. Funds will be allocated to the National Domestic Violence Hotline, including a sub-award to StrongHearts Native Helpline. This support will allow both hotlines to provide services remotely, such as immediate crisis intervention, safety planning, information and referrals, advocacy, and resources to anyone affected by domestic and dating violence throughout the United States and specifically for Native American victims to receive culturally appropriate help and peer support.

- Funds, which are expected to be awarded in the third quarter, should be used for the provision of remote intervention services provided by telephone, text, or digital communication and for the materials, supplies, equipment, and software to carry out these remote services.

#### Family Violence Prevention and Services (\$45 million) –

A total of \$45 million is provided to support Family Violence Prevention and Services formula grantees with disaster-related activities without regard to matching requirements. Funds will be allocated to eligible states, state domestic violence coalitions, tribes, and territories based on the formula. The emphasis will be on direct supportive services, immediate shelter, and temporary housing consistent with statutory purposes for victims of family, domestic, and dating violence and their dependents.

In addition, 2.5 percent or \$1.1 million, will be used for federal administration, technical assistance, and oversight. Funds may be used to pay salaries of federal employees.

- ACF expects that grantee funds, which are expected to be awarded in the third quarter, will be used for direct crisis intervention services, including counseling, off-site assistance, tele-health, peer support, and in-person assistance; shelter and temporary housing, including use of hotels/motels, short-term rentals, rental assistance, and nominal relocation expenses to ensure victim safety and paid directly to vendors; and materials, supplies, equipment, and software to carry out remote services and provide safe and sanitary residential facilities.

#### Runaway and Homeless Youth (\$25 million) –

The Runaway and Homeless Youth Program will issue supplemental funding to support the enhanced needs of current grantees during this time based on information they provide. This

could include the support of the increased need for shelter and supportive services for youth who are returning to homelessness and for the use of drop-in centers and the innovative techniques for conducting outreach to youth on the streets. Additionally, up to 6 percent may be used to support the administration of these grants.

Supplemental funds will be provided to grantees without regard to matching requirements.

Child Welfare Services (\$45 million) –

A total of \$45 million is provided to make grants to the agency in each state, territory, or tribe responsible for the Child Welfare Services program. Funds will be used to prevent, prepare for, or respond to the coronavirus and may also be used to restore amounts, either directly or through reimbursement, for costs already incurred. Grantees may use the funds for a broad range of child welfare activities consistent with program purposes, which include:

- Protecting and promoting the welfare of all children;
- Preventing the neglect, abuse, or exploitation of children;
- Supporting at-risk families through services that allow children, where appropriate, to remain safely with their families or return to their families in a timely manner;
- Promoting the safety, permanence, and well-being of children in foster care and adoptive families; and
- Providing training, professional development, and support to ensure a well-qualified child welfare workforce.

Federal Administration (\$7 million) –

A total of \$7 million will support federal administrative expenses for those ACF programs not given authority to use supplemental appropriations for these purposes, including support for personnel and associated rent, overhead, and security fees; information technology support; and resources needed to ensure proper oversight and monitoring of grant and contract activities. Some funds may be used to pay salaries of federal employees, but decisions have not been made at this time.

## ADMINISTRATION FOR COMMUNITY LIVING

### Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Home and Community-Based Supportive Services	200.000
Home-Delivered Nutrition Services	480.000
Native American Nutrition and Supportive Services	20.000
Family Caregiver Support Services	100.000
National Long-Term Care Ombudsman Program	20.000
Aging and Disability Resource Centers	50.000
Independent Living—Centers for Independent Living	85.000
<b>Total, ACL Coronavirus Funding</b>	<b>955.000</b>

ACL programs provide funding to States, Tribes and community-based organizations for an array of services and supports that work together to make it possible for older adults and people of all ages with disabilities to live independently in their homes and communities. These include services such as transportation to doctors, grocery stores, and financial institutions and support for family caregivers. Programs specifically for older adults provide meal delivery and related services in their homes and in a variety of community settings (e.g., senior and community centers, churches, centers, and school and hospital cafeterias) and support ombudsmen who advocate for them if they are in an institution. Programs specifically for individuals with disabilities provide independent living skills training, systemic and individual advocacy training, and services and other activities that support community integration and prevent institutionalization. ACL funding also supports aging and disability resource centers (ADRCs), which assist older adults and people with disabilities with connecting to the services they need to live in the community. ADRCs also assist both populations with transitioning from institutions back into the community.

Community measures to slow transmission of COVID-19, such as sheltering in place, self-quarantine and social distancing have resulted in suspension of many services that are typically provided in community settings. The precautions also have left many family caregivers unable to support their loved ones as they normally would. Consequently, demand for these services has increased significantly, and there is an urgent need for alternate methods for delivering them.

The emergency funding will enable communities to provide services to more people and support innovative alternatives for delivering them (such as “grab and go” meals, or temporary home delivery of meals, for older adults who typically rely upon the meal they receive at their local senior center).

Most of the \$955 million provided to ACL under the Coronavirus Aid, Relief and Economic Security (CARES) Act will be awarded as formula grants to States or Tribes, giving them maximum flexibility to determine the best approaches to meeting local needs. \$50 million will be awarded through an accelerated competitive process to ADRCs, and \$85 million will be allocated by a formula and provided directly through grants to Centers for Independent Living, which are community-based organizations that support individuals with disabilities in

participating in all facets of community living. None of the supplemental funding will be used to support either Federal administration or Federal FTE.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Aid, Relief and Economic Security Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$955 million included for the Administration for Community Living in the Coronavirus Aid, Relief, and Economic Security Act.

### **Planned Activities**

#### **Home and Community-Based Supportive Services (HCBSS) (\$200 million) –**

- Funding for HCBSS will allow more seniors to receive a greater amount and range of flexible services that allow them to shelter-in-place or self-quarantine and that support social distancing to help minimize their exposure to COVID-19. These include personal care homemaker and chore services, transportation to grocery stores, banks or doctors when necessary, and case management. Additionally, states and area agencies on aging will have the flexibility to provide specific services intended to mitigate some of the isolation that might occur, including virtual friendly visiting, telephone reassurance, and the use of electronic communications technologies (e.g., Skype, FaceTime, Zoom) to promote face-to-face interaction with family members and program staff. States and area agencies on aging will have the flexibility to use these additional funds to enhance programs and services designed to provide health screening (including mental and behavioral health screening and falls prevention services screening) to detect or prevent (or both) illnesses and injuries that occur most frequently in older individuals.
- These funds can also support activities that continue to be coordinated at and by senior centers, such as serving as the community hubs for coordination of the array of supportive services, recruitment and coordination of volunteers, initiation and deployment of virtual evidence-based chronic disease and falls prevention programming as well as programs and activities to keep seniors connected and engaged and avoid social isolation and depression.

#### **Home-Delivered Nutrition Services (\$480 million) –**

- Formula grant awards will allow States to deliver meals and related services directly to older adults age 60 and older. This could include both frail seniors and those needing to remain in their homes to avoid the risk of contracting the virus.
- The Coronavirus Aid, Relief, and Economic Security Act provided \$480 million for nutrition services, and gave States authority to transfer up to 100% of these funds between Home-Delivered and Congregate Nutrition programs. ACL allocated the \$480 million to Home-Delivered Nutrition, recognizing the need for people to stay at home

during the pandemic. States can use the transfer authority to provide meals and related services to adults age 60 and older through existing Congregate Nutrition programs as needed. This could include “drive-through” or “grab-and-go” meals.

- Together, these services will help to ensure adequate nutrition for seniors who typically would participate in meal programs at congregate sites that have been closed due to social distancing measures or who are limiting their exposure to the coronavirus by avoiding supermarkets, restaurants and other venues where food would normally be available.

#### Native American Nutrition and Supportive Services (\$20 million) –

- Formula grant awards will allow Tribes and Tribal Organizations to provide meals and related services, such as transportation directly to Native American elders, whose access to meals have been restricted by the coronavirus. Meals and related services will be provided in the most appropriate setting during this public health emergency.

#### Family Caregiver Supportive Services (\$100 million) –

- This program makes available a range of support services, such as information, counseling, respite care, and training that assist family and informal caregivers, including grandparents and older relative caregivers to care for their loved ones at home. Studies have shown that these supports can reduce caregiver depression, anxiety, and stress, all of which are expected to increase as a result of the need to deal with social distancing, and the risks imposed on older Americans in particular by the coronavirus pandemic. Emergency funds are expected to be used by States to expand these services to more of the people caring for older adults, individuals of any age with dementia, and grandparents and older relatives raising children, during the pandemic.

#### Long-Term Care Ombudsman Program (\$20 million) –

- This program supports the efforts of the staff and volunteer representatives of Long-Term Care Ombudsman Offices to provide consumer advocacy for the approximately 3 million individuals who reside in over 74,000 long-term care facilities across the country. This population has already been hard hit by, and is particularly susceptible to, COVID-19. These funds will support acquisition of urgently needed technologies to enable virtual visitation and advocacy services, recruitment of Ombudsman staff and volunteers, and enhanced training on how to continue Ombudsman advocacy to effectively address the needs of older Americans in these facilities during this pandemic.

#### Aging and Disability Resource Centers (ADRCs) (\$50 million) –

- This funding will enable ADRCs to provide critical access functions to long-term services and supports to those populations most at risk of COVID-19 and mitigate adverse effects related to the pandemic such as social isolation, reduced access to nutritional supports, personal care services, and support to transition from nursing home or hospital to home.

- ADRC funds will be awarded through a competitive review process. ACL has developed an emergency application process to expedite the issuance of these awards; all states are eligible to apply. The expedited process includes the posting of a FOA for one week, a condensed application package, and internal objective review. The funding distribution for each state will be based on (1) the number of individuals in each state who are age 60 and older (Source: US Census, 2018), and (2) the number of individuals of all ages in each state who have disabilities (Source: American Community Survey, 2017). Funding will go to the lead state agency designated by the state overseeing ADRCs.
- ACL’s expectation is that ADRCs will respond to the unprecedented increased demand for application assistance, assessments, person-centered planning, care coordination, transitional services and follow-up for those populations most at risk, such as older adults, persons with disabilities and their caregivers who are seeking service options through this emergency.
- Funds will be used to increase and enhance services and functions specifically to overcome access challenges resulting from COVID-19 including:
  - *Virtual assessments* for social determinants of health needs (standardized screenings);
  - *Care transitions* (hospital-to-home and nursing home-to-home) follow-up;
  - State or local *Information and Referral* to community based services;
  - Virtual short and long-term *Care Coordination*;
  - *Tele-functional and clinical assessments*; and
  - *Person-centered plan development*.

Independent Living—Centers for Independent Living (CILs) (\$85 million) –

- Individuals with disabilities are at risk for losing the supports they need to remain living independently; this may be the result of loss of direct service support, hospitalization, or temporary placement in institutional settings.
- Funding will be provided by a formula through supplemental grants to existing Centers for Independent Living (CILs) to provide direct and immediate support and services to individuals with disabilities who are experiencing disruptions to their independent, community-based living due to the COVID-19 pandemic.
- CILs will provide remote and in-person support to ensure individuals with disabilities can transition back home and put back in place all necessary resources and supports. Additional independent living skills may be taught, and connection to other resources, including protection and advocacy, will be leveraged.

**PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND**  
**Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**

*(Dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Assistant Secretary for Preparedness and Response	
<i>Medical Countermeasure Development</i>	<i>3,500.000</i>
<i>Strategic National Stockpile (SNS)</i>	<i>16,000.000</i>
<i>Medical Surge</i>	<i>1,060.000</i>
<i>ASPR Contingency</i>	<i>4,530.000</i>
<b>Subtotal, ASPR Coronavirus Funding</b>	<b>25,090.000</b>
Health Resources and Services Administration	
<i>Rural Health</i>	<i>180.000</i>
<i>Ryan White HIV/AIDS</i>	<i>90.000</i>
<i>Poison Control</i>	<i>5.000</i>
<b>Subtotal, HRSA Coronavirus Funding</b>	<b>275.000</b>
HHS Contingency	1,565.500
Telehealth	64.5
Provider Relief and Protection Fund	100,000.000
Office of Inspector General (OIG)	4.000
NASEM Study of Medical Product Supply Chain	1.500
Other Federal Agencies <sup>1</sup>	289.000
<b>Total, PHSSEF Coronavirus Funding</b>	<b>127,289.500</b>

<sup>1</sup>The planned activities described below do not include this funding which may be transferred as necessary to other federal agencies for necessary expenses related to medical care that are incurred to prevent, prepare for, and respond to coronavirus for persons eligible for treatment pursuant to section 322 of the Public Health Service Act, as amended, as determined by the Secretary of the recipient agency.

This plan reflects the allocation and planned uses of resources for the Public Health and Social Services Emergency Fund (PHSSEF) appropriation in the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Within the total of \$127.289 billion, \$25.4 billion will fund the Assistant Secretary for Preparedness and Response (ASPR) to continue the response to COVID-19. Funds will be used for Medical Countermeasure (MCM) development, to support procurement under the Strategic National Stockpile (SNS), and for Medical Surge in support of the State and Local response.

The PHSSEF appropriation provides \$275 million in discretionary resources to HRSA for rural health, Ryan White HIV/AIDS Program, and Poison Control Center activities. The plan also describes activities for funding appropriated to PHSSEF which HHS has decided to allocate to HRSA to support telehealth. This plan also describes activities for \$100 billion appropriated to PHSSEF to prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus, which will be carried out by HRSA.



HHS is closely coordinating across the Department to ensure that activities funded through the CARES Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

## **Planned Activities – Assistant Secretary for Preparedness and Response**

### **Medical Countermeasure (MCM) Development (at least \$3.5 billion)**

- Funds would be used to continue progress on the development of vaccines, therapeutics and diagnostics through safety and efficacy trials, and manufacturing validation.
- **Therapeutics** (\$1.35 billion development): Addressing the COVID-19 outbreak requires developing and making available, through ramping up manufacturing, therapeutics for individuals that are severely ill, as well as developing therapeutics for individuals that have mild/moderate disease to prevent them from progressing to severe disease. It also requires consideration for supply chain and domestic manufacturing to ensure availability of the drugs once they are successfully developed. Underpinning this strategy is the need to develop these therapies as quickly as possible, including using platform technologies, focusing on potential therapies that have previous clinical data, and running as many tasks in parallel as possible to expedite development. The following bullets highlight proposed activities that will be funded:
  - Screen existing monoclonal antibodies developed for other coronaviruses and development of new targeted monoclonal antibodies using platform technology that has been used to successfully license monoclonal antibodies for other diseases.
  - Advance one targeted monoclonal platform candidates identified in screening through manufacturing, non-clinical, and clinical trials.
  - Screen thousands of small molecule compounds with existing clinical data for activity against SARS-CoV-2.
  - For successful leads identified in the screening activity, support the (estimated) 2 lead candidates through the manufacturing, non-clinical, and clinical development pipeline. The focus will be on oral small molecules that are appropriate for individuals with mild/moderate disease to prevent their progression to severe disease.
  - Funding of novel therapeutic approaches with break-through potential to be available more rapidly than even traditional platform approaches.
- **Vaccines** (\$1.906 billion development): Currently, there are no vaccines to prevent COVID-19 infection. These requested funds will support advanced development of coronavirus vaccine utilizing vaccine platforms that support rapid development. (Estimated) five platforms will initially be funded with funding being shifted to those candidates that have the most promising data during the development process. Full scale manufacturing validation will also be completed.
  - Funding of novel vaccine approaches and platforms to accelerate vaccine availability, delivery, and administration. This includes innovative vaccine

platforms, and alternative delivery approaches to address a potential shortage of needles and syringes.

- The above cost is for development only and does not include vaccine procurement costs.
- **Diagnostics** (\$244 million): The funds will support development and FDA clearance of a variety of diagnostic assays for use in laboratories and other healthcare settings, including point-of-care, to detect COVID-19 infection, as well as identify individuals that have been previously infected. The following bullets highlight proposed activities that will be funded:
  - FDA clearance of multiple (estimated 4-6) different assays for COVID-19 infection that span the breadth of diagnostic capabilities, from high-throughput devices in commercial clinical labs, to large point of care, yet portable to handheld point of care.
  - Additional investment in and acceleration of availability of small handheld molecular diagnostics platforms suitable for use in non-traditional settings like screening stations.
  - Development of innovative next generation diagnostics to support an even more rapid, less invasive diagnostic capability.

### **Strategic National Stockpile (SNS) (\$16.0 billion)**

- **Ventilators:** ASPR will contract for production and delivery of portable mechanical ventilators to significantly increase the amount of ventilators available from the Strategic National Stockpile. The COVID-19 response highlights the exponential increase in patients needing ventilator support in pandemic scenarios. To meet these requirements across the nation, ASPR expects to acquire approximately 200,000 mechanical ventilators. Contracting vehicles will be structured to incentivize rapid production and delivery of units for immediate use, and may include options to produce and hold ventilators for direct deployment to areas of need. To return these ventilators to SNS inventory for future events, ASPR will also contract for reconditioning and ongoing preventive maintenance services for these items to ensure safe and effective use in the future.
- **Personal Protective Equipment:** Funds will continue to increase personal protective equipment (PPE) production capacity, distribute product to impacted States, and receive product into Strategic National Stockpile (SNS) inventory as excess becomes available beyond commercial market demands. Initial Supplemental funds allocated to SNS were used to secure incentive contracts with multiple manufacturers of N95 respirators to increase production and take delivery for immediate deployment or for stockpiling over the course of 18 months. With additional funding, ASPR will make strategic awards from an open and continuous solicitation to increase production and acquire additional critical personal protective equipment items, to include goggles, face shields, isolation gowns, surgical gowns, coveralls, face masks, surgical masks, and gloves. ASPR also plans to invest in decontamination technology to extend the life of PPE. Additional PPE items will be addressed through appropriate contracting vehicles to meet current needs of

the nation's healthcare system, and to grow a sustainable stockpile of these items against future needs.

- **Domestic Manufacturing Capacity:** Funds also will be used to develop domestic manufacturing capacity for PPE. This will ensure production of needed PPE continues unimpeded and can be prioritized for domestic use. Funds will award contracts for manufacturing construction, retrofit of facilities and for acquisition of PPE source materials as necessary to drive expansion of domestic manufacturing to meet the needs of the United States during a public health emergency.
- **Patient Care and Management of MCMs:** To meet the immediate and forecasted needs of COVID-19 patients with secondary conditions, ASPR will purchase additional products needed for continued care of hospitalized individuals. These include intravenous antimicrobials for treatment of secondary pneumonia, as well as airway management circuits, required pharmaceutical products and other ancillary supplies for sustained treatment of patients on existing and newly acquired mechanical ventilators. Examples could include sedatives, paralytics, dissociative anesthetics, pain management, vasopressors, IV fluids, as well as disposable ventilator ancillary supplies in addition to the ventilator circuits. High flow nasal cannula and other associated airway management supplies may also be needed. These products may be direct shipped from the vendor for immediate deployment upon receipt or delivered into SNS to fill future requests from state and local partners, dependent on the needs of the response.
- **Increased Storage and Management Capacity:** ASPR will contract for additional SNS inventory storage, maintenance and management services to receive, store and sustain additional medical countermeasures, medical devices, and other assets acquired through supplemental funding to enhance preparedness for emerging infectious diseases and other threats. Products required to meet Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) requirements for stockpiling, including the previously described personal protective equipment, require significantly more warehousing space than is currently available under existing contracts. Multiple additional warehouses will be required to store the newly acquired product and ensure strategic distribution across the country for rapid deployment of any required product to any location in the United States.
- **Transportation:** Funds will support deployment of SNS assets and movement of personal protective equipment, drugs and devices as required to support state and local requirements during the COVID-19 response.
- **Testing:** Funds will support supplies and contracted operations to establish and expand nationwide testing capacity for COVID-19.
- **Replenishment and Expansion of Deployable Caches and Kits:** ASPR will expand the caches and sets available to support deployment of Federal Medical Stations in Strategic National Stockpile inventory for rapid deployment. As demonstrated in the COVID-19 response, the finite resources of the existing caches may not be enough in the event of a nationwide response which strains and exceeds the capabilities of the healthcare sector. Additional caches and kits will be procured, assembled and maintained in SNS warehouses for use in the COVID 19 response, or in the event of a future nationwide crisis.
- **Enhanced Inventory Management System:** ASPR will explore options to acquire and implement a new integrated enterprise resource planning system for management of the expanded Strategic National Stockpile inventory. Lessons learned through the COVID-

19 response will inform the requirements for this new system, but the primary characteristics will be expected to support interoperability with reporting and data sharing functions across federal, state and local agencies, improved transportation and in-transit visibility interactions, and enhanced capabilities to support rapid selection, picking and loading of required materials with limited reliance on manual processes and work outside the system. Closing Gaps in SNS Requirements: ASPR will continue to fund storage, sustainment, and replenishment of product acquired through this sustainment over time. This supplemental funding will be managed to ensure sufficient quantities are allocated to sustainment and replenishment costs to maintain the increased quantities and capacity of the greatly expanded stockpile in future fiscal years.

### **Hospital Preparedness and Response Operations (\$1.06 billion)**

- **Hospital Preparedness Program (\$250 million):** ASPR will administer funding for HPP from the third COVID supplemental similarly to the way funds were distributed for the first \$100 million allocated from the first supplemental appropriation. The support will directly benefit the National Special Pathogen System across four different components making up this treatment network: National Emerging Special Pathogen Training and Education Center (NETEC); Regional Ebola and Other Special Pathogen Treatment Centers; Hospital Preparedness Program (HPP) Cooperative Agreement Recipients and their State/Jurisdiction Special Pathogen Treatment Centers); and, Hospital Associations.

Through these components, ASPR will provide funds to private sector health care systems to support the urgent preparedness and response needs of hospitals, health systems, and health care providers on the front lines of this outbreak in order to help prepare them to identify, isolate, assess, transport, and treat patients with COVID-19 or other special pathogens or persons under investigation for such an illnesses.
- National Emerging Special Pathogen Training and Education Center (NETEC)
  - Funding Mechanism: Administrative supplement to existing cooperative agreement
  - Anticipated Total Funding Level: \$5 million
  - Eligible Applicants: Limited to the current NETEC consortium: Emory University, University of Nebraska Medical Center, and NY Health and Hospitals Corporation/Bellevue
- Regional Ebola and Other Special Pathogen Treatment Centers
  - Funding Mechanism: Administrative supplement to existing cooperative agreement
  - Anticipated Total Funding Level: \$3.5 million
  - Eligible Applicants: Limited to the current 10 Regional Ebola and Other Special Pathogen Treatment Centers
- HPP Annual Award Recipients
  - Funding Mechanism: Administrative supplement to existing cooperative agreement
  - Anticipated Total Funding Level: \$116.5 million.
  - Eligible Applicants: 62 public health department recipients in the 50 states, the District of Columbia, three directly-funded cities, and the U.S.

territories and freely associated states and their 59 state or jurisdiction special pathogen treatment centers

- Hospital Associations
  - Funding Mechanism: Administrative supplement to existing cooperative agreement
  - Anticipated Total Funding Level: \$125 million
  - Eligible Applicants: 53 hospital associations in all states, the District of Columbia, New York City, and Puerto Rico
- Workforce Modernization and Telehealth Access and Infrastructure in Emergency : To enhance access to digital health care delivery through workforce training and infrastructure development in the provision of digital health care in situations of public health emergency. Addressing vulnerable population’s health care needs and reducing the demand on acute health care facilities; improving digital health infrastructure; and, enhancing workforce safety, training, and capacity.
- Emergency Medical Management and Field Operations (\$525 million)
  - Funds will be used to support Emergency Support Function 8 – Health and Medical team deployments, logistics, surge staffing, continuity of operations, and expanded information technology and communications for the SOC and Incident Management Team field components. ESF-8 support will be provided to State and local jurisdictions needing support for quarantines, screening, hospital decompression, patient movement, and acute and community medical care for an estimated duration of three to six months.
  - Funds also will be used to help provide surge capability to hospitals and other healthcare facilities. Funds will procure fold out rigid temporary shelter systems that will expand deployable capabilities to protect vulnerable populations in large scale responses. These shelter systems will serve as drop in mobile medical facilities permitting a broad scope of medical capabilities in a sterile environment for emergent needs when local capacity is exhausted or inactive, with capacity to treat a number of indications to high levels of severity.
  - Resources will support high-priority patient testing efforts.
  - In addition, funds will procure high-acuity kits (HAK) to expand the capability of Federal Medical Shelters in the SNS to provide high levels of care to patients severely impacted by disease and respiratory distress.
- Novel Distribution of Medical Countermeasures (\$110 million): Development of capabilities to ensure rapid deployment and dispensing of medical countermeasures or other materials during emergencies. This is inclusive of, but not limited to, alternate delivery methods and dispensing solutions and the development of alternative delivery platforms for pharmaceutical, vaccine and biologic administration.
- Innovation for Rapid MCM Deployment (\$100 million): Funds will expand on-going efforts to accelerate API and biologics availability for end-to-end pharmaceutical, vaccine and/or biologics production in small-scale, modular, continuous manufacturing platforms for rapid medical countermeasure deployment.

- Pandemic Forecasting and Situational Awareness (\$45 million): To develop capabilities that bring together deep learning, Artificial Intelligence and Machine Learning applications to forecast disaster impacts and automate replenishment of supplies during pandemics and disasters.
- Patient Aeromedical Transportation (\$30 million): Support critical transport of COVID-19 patients as well as transport of related supplies.

### **ASPR Contingency (\$4.53 billion)**

- ASPR will allocate contingency funding as resource needs arise. ASPR anticipates funding will support MCM development and Strategic National Stockpile (SNS) activities.

## **Planned Activities – Health Resources and Services Administration**

### **Rural Health (\$180 million)**

#### Rural and Critical Access Hospitals (CAHs) (\$150.67 million)

- Provides support to small rural and Critical Access Hospitals (CAHs) which are seeing increased demands for clinical services and equipment, as well as experiencing short-term financial and workforce challenges related to responding to meeting the needs of patients with the COVID-19 seeking care at their facilities. These funds would be administered through the Small Rural Hospital Improvement Program, which can provide emergency funding support to CAHs and non-CAH rural hospitals with less than 50 beds. This approach would provide funding directly to the states to target those rural hospitals and the communities they serve who are facing the greatest strain from this crisis.

#### Telehealth (\$11.6 million)

- Supports rural and underserved communities to leverage telehealth technology to meet an increasingly expanded demand related to COVID-19. This expansion would increase the ability of the Telehealth Resource Centers (TRCs) to provide technical assistance to communities as they rapidly increase their use of telehealth services or deploy new telehealth services. The technical assistance would include hands-on technical support in areas such as equipment acquisition, payment policy, system design, licensing and credentialing.

#### Tribal Organizations (\$15 million)

- Under the CARES Act, HRSA's Federal Office of Rural Health Policy (FORHP) is appropriated money for a new program to provide resources to tribes, tribal organizations, urban Indian health organizations, and health care service providers to tribes as they continue to provide needed healthcare services during the COVID-19 outbreak. Technical assistance will also be provided to these grantees.
  - HRSA plans to conduct a new grants competition and plans to award \$15 million worth of grants by mid-May.

## Program Administration (\$2.73 million)

### Tribal (\$2.03 million)

- FORHP will provide technical assistance through a contract to support tribal grantees in the implementation of their grant awards. HRSA plans to set aside \$0.8 million (over 2 years) for the technical assistance contract.
- As the Tribal program is a new grant program, there will be costs associated with conducting new grant reviews and adding the program to the HRSA IT structure, including processing grant awards and monitoring program performance.
- Two FTEs are required to serve as project officers and program coordinators for planning, implementing, monitoring, coordinating, and analyzing grantee performance.

### Other Costs (\$0.7 million)

- One FTE is required to serve as a program coordinator for planning, implementing, monitoring, coordinating, and analyzing supplemented and new health programs to assess their success in achieving objectives for various initiatives. The FTE will also provide statistical consultation and data management for the Small Rural Hospital Improvement Program, Telehealth Resource Centers, and tribal grantees in response to new funding and programs targeting COVID-19 relief.
- Costs will be incurred to update the grants management and performance reporting systems for both the Telehealth Resource Centers and the Small Rural Hospital Improvement Program required by new reporting requirements associated with supplemental grants.

## **Ryan White HIV/AIDS** (\$90 million)

A high percentage of people with HIV are older; have multiple co-morbidities including cardiovascular disease, pulmonary disease, and diabetes; history of smoking; and underlying immunosuppression. This puts them at greater risk of severe COVID-19 disease and in greater need of social distancing. Ryan White HIV/AIDS Program patients are also much more likely than the general population to live below the federal poverty line, thus requiring increased assistance. The funding would be directed to clinics and community based organizations, city/county health departments, state health departments, and the AIDS Education and Training Centers (AETCs) for extended operational hours, increased staffing hours (overtime), additional equipment, workforce training and capacity development, and services such as home delivered meals and transportation.

## **Ryan White HIV/AIDS Program Parts A, B, C, D** (\$85.3 million)

- Making grant awards to current Parts A, B, C, and D recipients, based on a funding methodology for each Part that focuses on the number of clients served (A-C) or base award amount (Part D). Recipients may use the funding for costs allowable under the Ryan White HIV/AIDS Program, including, but not limited to, funding for:

- Extended hours of operation of clinical and support sites required for the COVID-19 response, and additional equipment needs.
  - Increased demands for emergency housing, home delivered meals, transportation, and other costs to support social distancing for patients.
  - Increased demand for medication, medical services, and essential support services
  - Reimbursement for costs incurred before the award for responding to the COVID-19 pandemic.
- ADAP Technical Assistance Cooperative Agreement (\$100,000)
    - To provide increased technical assistance for AIDS Drug Assistance Program to address changes in client eligibility and recertification processes and formulary/medication management in response to the pandemic.

**Ryan White HIV/AIDS Program AETC (\$3.6 million)**

- Awards to the existing Regional AETCs, the National Clinical Consultation Center, the National Coordination and Resource Center, and the National HIV Curriculum. Recipients may use the funding for technical assistance and training to clinicians to support their response to the COVID-19 pandemic, particularly as it pertains to people with HIV. Activities may include, but are not limited to:
  - Online, remote, and in person training;
  - Development and dissemination of resources for clinicians; and
  - Enhancing hours of operation and staffing to respond to clinicians' educational and consultation needs regarding COVID response.

**Data Reporting (\$1 million)**

- To ensure accountability of award funding, HRSA will need a have a robust data collection and reporting mechanism.

**Poison Control (\$5 million)**

**Poison Control Center Grant Program (PHS Act, Section 1273) (\$4.8 million)**

- Funds population-based, supplemental grant awards to existing HRSA-funded Poison Control Centers (PCCs) to improve their capacity to respond to increased calls due to the national Coronavirus emergency.
- This one-time funding will be awarded to 52 existing PCC grantees nationwide.

**National Toll-Free Number (PHS Act, Section 1271) (\$0.2 million)**

- Provides increased funding to the national toll-free poison control hotline. Estimates 26 percent increase in call volume through the National Toll-Free Number due to the Coronavirus. This estimate is based on data provided by the American Association of Poison Control Centers that reflects a 26 percent increase in call volume from state and other local sources since January 1, 2020 due to the Coronavirus.



## **Telehealth (\$64.5 million)**

### **Telehealth Website**

HRSA will oversee the development of a telehealth website ([www.telehealth.gov](http://www.telehealth.gov)) to provide links to informational resources for telehealth providers and resources for individuals seeking remote healthcare. HRSA plans to fund this website through two IAAs. The first IAA will be with HHS's Office of the Chief Information Officer (OCIO), OCCPO to build the website infrastructure, hosting, and analytics. The second IAA will be with the Program Support Center (PSC) to support the website application development and project management. HRSA's Federal Office of Rural Health Policy will provide subject matter expertise to OCIO, OCCPO and PSC through the development, launch, and maintenance of the website. (Authority: Coronavirus Aid, Relief, and Economic Security Act, P.L. 116-136)

### **Telehealth Access and Infrastructure:**

HRSA would support a range of efforts to support safety-net health care providers who are facing a number of emerging financial, administrative, and organizational challenges as they quickly adapt to remote service delivery. The proposal addresses the remote health care needs of the vulnerable maternal and child populations, and has a clinical learning piece to support clinicians as they continue to scale up remote service delivery capability to deal with the national coronavirus emergency.

- **Telehealth Gateway Promotional Campaign**

HRSA will fund a new contract to promote the telehealth website to potential telehealth providers. This will be a national campaign to ensure that providers are aware of the website and its ability to connect patients to telehealth providers. HRSA's Federal Office of Rural Health Policy will manage this contract. . (Authority: Coronavirus Aid, Relief, and Economic Security Act, P.L. 116-136)

- **Licensure and Credentialing**

HRSA will provide funding to two existing Licensure Portability Grant Program grantees to assist telehealth clinicians nationally on licensure and credentialing issues to meet the emerging needs with the COVID-19 public health emergency. This effort will reduce the burden on clinicians and speed the availability of clinicians to provide telehealth services in additional sites. The grantees would work with the clinician and state licensing boards as well as national compacts.

- **Telehealth Services for Prenatal and Maternal and Child Health**

HRSA will provide funding to increase capability and capacity (including provision of supplies, training, and other supports) to providers and families in order to promote access to telehealth and distant care services related to prenatal care and pregnancy monitoring, labor and delivery support (e.g., doulas), virtual postpartum care and infant care/support, remote home visiting, and support for children and youth with special healthcare needs (including autism) so that primary care and home visiting functions can

occur away from physical sites. In particular, the program will focus on ensuring access for vulnerable maternal and child health populations. HRSA will make awards to current grant recipients with expertise in maternal and child health as well as the ability to implement projects with nationwide scope.

- Health Workforce Modernization

HRSA will provide funding for grants to current recipients to reformat clinical training of students and front line clinicians, namely physicians, nurses, physician assistants, allied health and other high-demand professionals to provide telehealth and other distant care services related to COVID-19 and other essential care during the crisis. This proposal would focus on students and clinicians currently involved in health profession training who will be trained to provide telehealth-enabled COVID-19 screening and testing, case management and outpatient care and to also maintain primary care functionality away from physical sites, especially for COVID-19 positive, quarantined, elderly and special populations.

#### Administrative Costs

HRSA will manage the contract for the Telehealth Website Promotional Campaign and to provide subject matter expertise needed to coordinate and inform the content for the website.

#### **Provider Relief and Protection Fund (\$100 billion)**

The Coronavirus Aid, Relief and Economic Security (CARES) Act provides HHS \$100 billion under the Public Health and Social Services Emergency Fund (PHSSEF), to administer a “Provider Relief and Protection Fund” (PRF). The Act provides funds to remain available until expended to prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus. The Secretary of HHS has designated the Health Resources and Services Administration (HRSA) to administer these funds. HRSA will allocate and distribute the appropriated funds for COVID-19 related expenses to eligible health care providers in a manner that is fast, fair, simple and transparent.

#### General Distribution (\$50 billion)

HRSA will allocate approximately \$50 billion to eligible providers through a general distribution. HRSA will award a contract to a vendor that will make payments directly to eligible health care providers beginning in April 2020. HRSA will develop a payment methodology that will include an estimated amount for immediate disbursement based on a formula derived using historical payments under Medicare fee-for-service and providers’ total revenues. Providers receiving funds will attest to/certify eligibility, allowable costs, and availability of records. Attestation will be made through a portal found at: <https://covid19.linkhealth.com/#/step/1>. HRSA will disburse funds under the general distribution until all funds are expended.

#### Other (\$50.00 billion)

HRSA will work to identify additional provider needs and distribute funds to meet those needs, including targeted distribution, treatment for the uninsured and a reserve distribution.

- Targeted Distribution

HRSA will allocate funding through a targeted distribution, which will include targeted funding to COVID-19 hotspots, rural providers, providers of services with lower shares of Medicare reimbursement or who predominantly serve the Medicaid population.

HRSA will award a contract to a vendor that will make payments to eligible health care providers beginning in April 2020. Payments will be made on a rolling basis. Examples of eligible health care providers may include: federally qualified health centers, rural health clinics, primary care practices, critical access hospitals, Children's Hospitals, Indian Health Service/Tribal/Urban Indian health care facilities, community-based service providers, behavioral health providers, and nursing homes. HRSA will develop a payment methodology to determine the estimated payment. As with the general distribution, providers receiving funds must sign an attestation confirming receipt of the funds and agreeing to the terms and conditions of payment. HRSA will disburse funds under the targeted distribution until all funds are expended.

- Treatment for the Uninsured

HRSA will distribute reimbursements for claims under the Treatment for the Uninsured Program and in coordination and alignment with the Testing for the Uninsured activities authorized and appropriated separately under the Families First Coronavirus Response Act, 2020. HRSA will award a contract to a vendor who will make reimbursements for claims to eligible entities beginning in May 2020. Reimbursements will be made on a rolling basis directly to eligible providers for claims that are attributable to the treatment of COVID-19 for uninsured individuals. Providers receiving claims reimbursement will agree to accept reimbursement from the Treatment for the Uninsured Program as payment in full and not subsequently balance bill patients, nor bill patients for any cost-sharing. Providers submitting claims for reimbursements will also sign an attestation to patient(s) uninsured status and agreeing to the terms and conditions of reimbursement. HRSA will disburse funds under the Treatment for the Uninsured Program until all funds are expended.

- Reserve Distribution

HRSA will distribute funding through a reserve distribution. HRSA will award a contract to a vendor that will make payments to eligible health care providers beginning in July 2020. Payments will be made on a rolling basis. HRSA will develop a payment methodology to determine the estimated payment for health care related expenses or lost revenues that are attributable to the treatment of patients with COVID-19 and that have not been reimbursed from other sources, including: a) the general distribution, targeted distribution, and/or Testing or Treatment for the Uninsured Programs within the PRF; b) other sources of provider relief enacted in response to COVID-19; or c) statutory authorities offering provider relief that existed pre-COVID-19 on either a permanent or waived basis. Providers receiving funds will also sign an attestation confirming receipt of the funds and agreeing to the terms and conditions of payment. HRSA will disburse funds under the reserve distribution until funds are expended.

### Program Administration

HRSA will fund two claims processing contracts that will provide payments to health care entities and providers through the proposed reimbursement programs. The vendors will support the general, targeted, and reserve distribution, and claims reimbursements for the Treatment of the Uninsured Program. The contracts will also support the development, maintenance and management of claims processing systems including system integration, and data collection and reporting.

HRSA Funding will support additional FTEs to administer the PRF. In addition, HRSA anticipates awarding contracts to support program administration, including: attestation; system support; communications activities; auditing and compliance; program integrity; and general program management. This funding also supports a separate task order for analytic support needed to help determine assistance levels for providers.

### **Planned Activities – HHS Contingency (\$1.56 billion)**

As the COVID-19 pandemic rapidly evolves and the number of cases across the world and domestically continue to grow, HHS continues to monitor the situation and support response activities supported with additional emergency supplemental resources. HHS continues to identify program flexibilities and is working to eliminate obstacles to help support front line responders and overall response activities. HHS is assessing various potential additional activities that could be supported with emergency supplemental resources including but not limited to additional health care services, targeted coordination activities, and technical and infrastructure capacity to support preparedness and response. In addition, funding could be used to support potential reimbursements to the Department of Veterans Affairs.

### **Planned Activities – Office of Inspector General**

#### Office of Inspector General (OIG) Oversight (\$4 million)

- A total of \$4 million will support the Office of Inspector General (OIG) to oversee HHS efforts to combat the COVID-19 coronavirus, including oversight of the emergency supplemental funding provided to HHS's Operating Divisions. OIG reviews will help ensure proper oversight and management by HHS agencies, including oversight of expenditures for needed health and human services to combat the COVID-19 coronavirus. This would include assessing the efficiency and effectiveness of HHS activities, grants, contracts, and providers. It would include assessing internal controls and procedures for ensuring the safety and provision of necessary resources to individuals or entities impacted by the COVID-19 coronavirus. These reviews will also assess the impact of COVID-19 related regulatory and guidance changes, with a focus on how these changes effect program integrity, including improper payment rates and collections.
- OIG typically obligates 4% as an organization on overhead/administration costs. OIG anticipates that work to support coronavirus preparedness and response will require a similar level of administrative costs.

**Planned Activities – NASEM Study of Medical Product Supply Chain (\$1.5 million)**

- Supports a HHS agreement with the National Academies of Sciences, Engineering, and Medicine to examine and report on the security of the United States medical product supply chain.

**Department of Health and Human Services**

**Paycheck Protection Program and Health Care Enhancement Act Spend Plan**

**May 22, 2020**

/JEN MOUGHALIAN/

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Jen Moughalian  
Principal Deputy Assistant Secretary

## INTRODUCTION

The Paycheck Protection Program and Health Care Enhancement Act Spend Plan, enacted April 24, 2020 (Public Law 116-139), provided \$100 billion in emergency supplemental funding to the Department of Health and Human Services (HHS) for Coronavirus preparedness and response activities.

The Act allocated \$100 billion to the Public Health and Social Services Emergency Fund (PHSSEF). Within this total, Congress directed transfers to the following agencies: \$22 million to the Food and Drug Administration (FDA), \$1 billion to the Centers for Disease Control and Prevention (CDC), \$1.8 billion to the National Institutes of Health (NIH), \$600 million to the Health Resources and Services Administration, and \$6 million to the Office of Inspector General.

The reporting requirements within the Paycheck Protection Program and Health Care Enhancement Act (Public Law 116-139) state:

SEC. 101. The requirements, authorities, and conditions described in sections 18108, 18109, and 18112 of division B of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136) shall apply to funds appropriated in this Act to the Department of Health and Human Services.

SEC. 18112. Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall provide a detailed spend plan of anticipated uses of funds made available to the Department of Health and Human Services in this Act, including estimated personnel and administrative costs, to the Committees on Appropriations of the House of Representatives and the Senate: Provided, That such plans shall be updated and submitted to such Committees every 60 days until September 30, 2024: Provided further, That the spend plans shall be accompanied by a listing of each contract obligation incurred that exceeds \$5,000,000 which has not previously been reported, including the amount of each such obligation.

The following spend plan details the planned uses of the supplemental funds appropriated to HHS. With these resources, HHS will support a comprehensive response to the COVID-19 outbreak, including expanding support for eligible health care providers for health-related expenses or lost revenue, and accelerating development and availability of diagnostics to ensure State, local, and Federal entities are able to prepare for, prevent, and respond to COVID-19 and its impact on the health and safety of the American public.

## **HHS OVERVIEW**

To respond to the growing global presence of COVID-19, the United States has supported a government-wide response to combat the virus and limit the negative health outcomes which can result. HHS has worked, and continues to work, with partners across the Federal government, the states, and the private sector. Activities include aiding domestic and international public health preparedness and response efforts; conducting public health surveillance, epidemiology, and laboratory testing; quarantining individuals who might have been exposed to the virus and isolating those who contracted the virus; training health care workers; advancing the development, testing, and availability of new vaccines, therapeutics, and diagnostics; advancing manufacturing enhancements; procuring and deploying necessary medical supplies; and providing social services and supports to at-risk populations such as older adults, persons with disabilities, American Indians/Alaska Natives, children, and individuals with substance use disorders.

Building on activities funded under the first, second and third COVID-19 supplementals, funding appropriated to HHS under the Paycheck Protection Program and Health Care Enhancement Act, will support activities across the Department to enhance ongoing efforts and continue a comprehensive and coordinated response to address the impact of COVID-19.



**PUBLIC HEALTH AND SOCIAL SERVICES EMERGENCY FUND**  
**Fourth Supplemental**  
**Paycheck Protection Program and Health Care Enhancement Act**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Provider Relief and Protection Fund	75,000.00
Allocations to State, Local, Tribal and other entities	
<i>Centers for Disease Control and Prevention</i>	10,250.00
<i>Indian Health Service</i>	750.00
<b>Subtotal, Allocations to State, Local, Tribal and other entities</b>	<b>11,000.00</b>
Medical Countermeasure (MCM) Development – Diagnostics	1,000.00
Testing for the Uninsured	1,000.00
Rural Health Clinics Testing	225.00
Agency Transfers	
<i>Health Resources and Services Administration</i>	600.000
<i>Centers for Disease Control and Prevention</i>	1,000.00
<i>Food and Drug Administration</i>	22.00
<i>National Institutes of Health</i>	1,806.00
<i>Office of Inspector General</i>	6.00
<b>Subtotal, Agency Transfers</b>	<b>3,434.00</b>
Other Activities	8,341.00
<b>Total, PHSSEF Funding</b>	<b>100,000.00</b>

This plan reflects the allocation and planned uses of resources for the Public Health and Social Services Emergency Fund (PHSSEF) appropriation in the Paycheck Protection Program and Health Care Enhancement Act. Within the total of \$100 billion, \$75 billion will be directed to the Provider Relief and Protection Fund, \$11 billion will be allocated to State, Local, Tribal and other entities, \$1 billion will be allocated to medical countermeasure development, up to \$1 billion will be allocated to testing for the uninsured, and \$225 million will be allocated to rural health clinics testing. A total of \$3.434 billion will be transferred from the PHSSEF to the following agencies: CDC, HRSA, FDA, NIH and OIG. The remaining \$8.3 billion will be allocated to other testing activities.

HHS is closely coordinating across the Department to ensure that activities funded through the Paycheck Protection Program and Health Care Enhancement Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

## **Provider Relief and Protection Fund (\$75 billion)**

### **HRSA Planned Activities**

The Paycheck Protection Program and Health Care Enhancement Act provides HHS \$75 billion under the Public Health and Social Services Emergency Fund (PHSSEF), to administer a “Provider Relief and Protection Fund” (PRF). The Act provides funds to remain available until expended to prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus. The Secretary of HHS has designated HRSA to administer these funds. HRSA will allocate and distribute the appropriated funds for COVID-19 related expenses to eligible health care providers in a manner that is timely, fair, simple, and transparent. These funds are in addition to \$100 billion appropriated under the CARES Act for the same purpose and will be implemented in coordination with activities implemented using CARES Act PRF funding.

- **PRF Distributions**

Payments will be made on a rolling basis through a contract HRSA awarded in April 2020 to make payments to eligible health care providers. Examples of eligible health care providers may include: federally qualified health centers, rural health clinics, primary care practices, critical access hospitals, Children’s Hospitals, acute care hospitals, Indian Health Service/Tribal/Urban Indian health care facilities, community-based service providers, behavioral health providers, and nursing homes. HRSA will develop a payment methodology to determine the payment. Providers receiving funds must sign an attestation confirming receipt of the funds and agreeing to the terms and conditions of payment.

- **Treatment for the Uninsured**

HRSA will distribute reimbursements for claims under the Treatment for the Uninsured Program and in coordination and alignment with the Testing for the Uninsured activities authorized and appropriated separately under FFCRA. HRSA has awarded a contract to a vendor who will make reimbursements for claims to eligible entities beginning in May 2020. Reimbursements will be made on a rolling basis directly to eligible providers for claims that are attributable to the treatment of COVID-19 for uninsured individuals. Providers receiving claims reimbursement will agree to accept reimbursement from the Treatment for the Uninsured Program as payment in full and not subsequently balance bill patients, nor bill patients for any cost-sharing. Providers submitting claims for reimbursements will also sign an attestation to patient(s’) uninsured status and agreeing to the terms and conditions of reimbursement.

- **Program Administration**

HRSA funds two claims processing contracts that provide payments to health care entities and providers through the reimbursement programs. The vendors support the funding distributions and claims reimbursements for the Treatment of the Uninsured Program. The contracts will also support the development, maintenance and management of claims processing systems including system integration, and data collection and reporting.

Funding will support FTEs to administer the PRF. In addition, HRSA anticipates awarding contracts to support program administration, including: attestation; system support; communications activities; auditing and compliance; program integrity; and general program management. This funding also supports a separate task order for analytic support needed to help determine assistance levels for providers.

### **Allocations to State, Local, Tribal and other entities (at least \$11 billion)**

#### IHS Planned Activities

- Testing and Testing-Related Activities (\$750 million)
  - IHS, Tribal, and Urban Indian Health Programs
    - For IHS-operated health programs, IHS provided allocations to IHS Area Offices and IHS service units for COVID-19 testing and testing-related activities.
    - For Tribal Health Programs, IHS provided supplements to Indian Self-Determination and Education Assistance Act (ISDEAA) Title I and Title V contracts and compacts for COVID-19 response activities.
    - For Urban Indian Health Programs, IHS provided supplements to existing FAR contracts for COVID-19 testing and testing-related activities.
  - National Service Supply Center
    - IHS will provide additional resources to the National Service Supply Center to procure COVID-19 tests, test kits, necessary personal protective equipment, and supplies.
  - Nation-wide Coordination Activities
    - IHS will conduct nation-wide coordination and support activities related to testing, contact tracing, surveillance and other testing-related activities.
    - In addition, to the resources described above, administrative costs will be supported from funds unallocated in this appropriation for testing activities.

#### CDC Planned Activities

- Awards to States, Territories, and Localities (\$10.25 billion)

Through grants to states, territories and localities using CDC's existing Epidemiology and Laboratory Capacity mechanism, these funds will support necessary expenses to develop, purchase, administer, process, and analyze COVID-19 tests, conduct surveillance, trace contacts and related activities. Funding allocations are determined based on the following methodology, to support all jurisdictions based on population, and to provide additional funding to those with high COVID-19 disease burden:

  - \$6 billion was awarded to States, localities, and territories according to the population-based, Public Health Emergency Preparedness grant formula.
  - \$4.250 billion was awarded to states according to a formula based on the proportion of total reported COVID-19 cases.
  - Funds may also be used for rent, lease, purchase, acquisition, construction, alteration, renovation, or equipping of non-federally owned facilities to improve State and local preparedness and response, and for the production of diagnostic, serologic, or other COVID-19 tests or related supplies.

- In addition to the resources described above, administrative costs will be supported from funds unallocated in this appropriation for testing activities.

## **Medical Countermeasure (MCM) Development – Diagnostics (at least \$1.0 billion)**

### ASPR Planned Activities

In March and April of 2020, industry partners, in part as a result of partnerships with ASPR, have substantially increased U.S. diagnostic test availability to inform patient care and to ease the worries of concerned citizens due to the COVID-19 outbreak. However, more tests are needed in coming months to support patient care, prepare for a potential second wave of this deadly disease, and get America back to work. With the funding provided under the Paycheck Protection Program and Health Care Enhancement Act, ASPR will provide funding to industry partners to develop even more diagnostic tests and to expand domestic test-manufacturing capacity, making more diagnostics test available.

The Biomedical Advanced Research and Development Authority (BARDA), along with industry partners, will expand existing product development programs and initiate new programs. Multiple funding mechanisms will be used, including advanced research and development contracts and other transaction authorities. Molecular, antigen, and antibody diagnostic tests will be developed, domestic diagnostic test and sample collection kit manufacturing capacity will be increased, the ability to automatically collect disease surveillance data will be improved, and support services needed to accelerate diagnostic test development will be provided.

Collaboration with HHS partners (CDC, FDA, and NIH), and DoD, will be required to initiate and successfully complete these programs. There is close coordination across HHS to ensure that activities funded through the Paycheck Protection Program and Health Care Enhancement Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$1 billion included for ASPR in the Paycheck Protection Program and Health Care Enhancement Act.

- Laboratory Molecular Diagnostics  
Molecular tests are the most effective for detection of acute SARS-CoV-2 infection. Industry partners, some with ASPR funding, have developed SARS-CoV-2 molecular diagnostics assays for use on most clinical laboratory instrument systems with extensive U.S. clinical laboratory placements. BARDA will provide additional funding to industry partners to develop multiplexed respiratory disease panels that include SARS-CoV-2 tests and other assays with potential to support early response, should another novel coronavirus outbreak occur. BARDA will also fund industry-partners to improve the performance of tests and test panels that achieve emergency use authorizations (EUAs) to meet the requirements for FDA clearance, perform the verification and validation tests required for regulatory filings, and complete regulatory filing up to and through FDA 510(k) clearance.

- Point-of-Care (POC) Molecular Diagnostics Several companies are developing novel hand-held sample-to-answer molecular diagnostic tests, initially targeted for the emerging home influenza diagnostics market. BARDA will fund select industry partners, that are sufficiently mature, to adapt their technology for detection of SARS-CoV-2 acute infection. These systems do not require separate extraction reagents, which have recently been in short supply. Priority will be given to systems that accept direct swab sample introduction and do not require any sample preparation or buffers. These tests will be especially useful in non-traditional near-patient testing settings, such as nursing home and correctional facility investigations, and for screening asymptomatic and symptomatic Americans. Funding will be provided to industry partners to develop additional tests to obtain EUAs, improve the performance of tests that achieve EUAs to meet the requirements for FDA clearance, perform the verification and validation tests required for regulatory filings, and complete regulatory filing up to and through FDA 510(k) clearance. Assays with potential utility in early response to other potential novel coronavirus outbreaks will also be developed.
- Antigen Detection POC Diagnostics Antigen detection POC diagnostics are not as sensitive or specific as molecular tests, but their lower cost, ease of use, and rapid results make them attractive for many diagnostics applications, including testing in pharmacies, and outbreak investigations in nursing homes and worksites. Due to their reduced sensitivity, they are best used with samples from patients who are symptomatic (likely to have higher concentrations of virus in respiratory tract). Funding will be provided to industry partners to develop additional SARS-CoV-2 tests to achieve EUAs, improve the performance of tests that achieve EUAs to meet the requirements for FDA clearance, perform the verification and validation tests required for regulatory filings, and complete regulatory filing up to and through FDA 510(k) clearance.
- Antibody Detection/Serology Laboratory Diagnostic Tests Accurate laboratory-based antibody tests, also called serology tests, are needed to identify persons who have been infected with SARS-CoV-2 virus, to identify persons who were infected but did not have symptoms, inform populations-based public health decisions, and identify people who were not infected and may be at greatest risk if exposed. Although there are many lateral flow tests being marketed in the U.S., FDA has not reviewed the vast majority of these, and their accuracy is unknown. Several manufactures have achieved EUA, but there is insufficient testing capacity with accurate tests to meet the need. Funding will be provided to industry-partners to develop high-throughput tests to EUA, improve the performance of tests that achieve EUA to meet the requirements for FDA clearance, perform the verification and validation tests required for regulatory filings, and complete regulatory filing up to and through FDA 510(k) clearance.
- Antibody Detection/Serology POC Diagnostics COVID-19 tests that utilize lateral flow and novel antibody/serology test technologies that are appropriate for use in POC and non-traditional settings (e.g., pharmacies, nursing homes, worksites) are needed. Even though one manufacturer has received an EUA for their lateral flow test, more tests that are very sensitive and do not non-cross react with antibodies to other seasonal coronaviruses are needed. Funding will be provided to industry partners to develop additional tests to achieve EUAs, improve the performance of tests that achieve

EUAs to meet the requirements for FDA clearance, perform the verification and validation tests required for regulatory filings, and complete regulatory filing up to and through FDA 510(k) clearance.

- Domestic Diagnostic Test Manufacturing Capacity Increases  
The importance of having test manufacturing capacity in the United States has become very apparent during the current COVID-19 outbreak. BARDA will provide funding to industry partners to increase their U.S. test, consumable, and instrument manufacturing capacity, to improve the health security of Americans, and in particular provide surge test and instrument manufacturing capacity for this and future disease outbreaks.
- Disease Surveillance Data Collection Capability Expansion  
Numerous POC test developers have implemented reporting capabilities in their instrument systems to report location, along with de-identified patient data to a central repository. BARDA will fund additional creation and expanded implementation of these capabilities for POC tests and ensure public health authorities receive data that can be used to inform public-health population based assessments (e.g., location, anonymized patient demographics and test results).
- Increase in Sample Collection Kit Availability  
The high number of nasopharyngeal, oropharyngeal and nasal swabs samples being collected worldwide for COVID-19 testing has exceeded global capabilities for manufacturing swabs and transport media. BARDA will fund industry partners to develop domestic U.S. swab sample collection kit manufacturing capacity, to improve the health security of Americans, and to meet the expanded testing demand for the current and future pandemic outbreaks.
- Services to Accelerate Diagnostic Test Development and Manufacturing Access to clinical respiratory samples known to be positive for SARS-CoV-2 virus or antigens, and blood samples positive for SARS-CoV-2 antibodies are critical to developing new tests and ensuring their accuracy. For common infections, diagnostics industry test developers typically acquire patient samples from clinical laboratories or biobanks; however, COVID-19 patient samples are not readily accessible, especially in the quantities needed to support large-scale diagnostic development and validation. If live virus is used to prepare samples, testing must be performed in Biosafety Level-3 facilities. Fully characterized qualification panels for use in final test validation, needed to complete FDA filings, are also needed to allow performance comparison between products. BARDA will fund industry partners, and in some cases interagency-partners with specialized capabilities, to collect and characterize COVID-19 patient samples, characterize and make these samples available to test developers, and perform evaluation of tests, where needed.

### **Testing for the Uninsured (up to \$1.0 billion)**

#### HRSA Planned Activities

HRSA has a contract with a vendor who will make reimbursements for claims to eligible entities beginning in May 2020. Reimbursements will be made on a rolling basis directly to

eligible providers for claims that are attributable to the testing of COVID-19 for uninsured individuals. Providers receiving claims reimbursement will agree to accept reimbursement from the Testing for the Uninsured Program as payment in full and not subsequently balance bill patients, nor bill patients for any cost-sharing. Providers submitting claims for reimbursements will also sign an attestation to patient(s') uninsured status and agreeing to the terms and conditions of reimbursement. In addition, these funds may support FTE and other costs to facilitate the administration of this emergency supplemental funding to include contract management, financial management, and claims payment review, validation, and processing.

### **Rural Health Clinics (\$225 million)**

#### **HRSA Planned Activities**

- **Rural Health Clinic Awards (\$225 million)**  
One-time allocation to the over 4,500 Rural Health Clinics (RHC) through the Provider Relief contract mechanism; more specifically the United. Funding will support increased COVID-19 testing capabilities for the detection, diagnosis, and treatment of COVID-19. Activities may include learning about testing, setting up alternate testing sites, processing test results, and arranging for the processing of test results.
- **Program Administration (\$1.6 million)**  
In addition, to the resources described above, administrative costs will be supported from funds unallocated in this appropriation for testing activities.
  - **Personnel Costs \$700,000:** Two FTEs to serve as program analysts for planning, implementing, and monitoring. The FTEs will also provide statistical consultation and data management for the program.
  - **Contracts costs \$350,000:** HRSA will be using existing contracts that support the Provider Relief and Protection Fund.
    - Support of contract to process claims that provide payments to RHCs through the proposed reimbursement program and support of a call center that will be utilized to provide tier one support (\$50,000)
    - Support of a data portal through which the RHCs can support testing data (\$300,000)
- **Technical Assistance \$500,000:** Support of technical assistance and tier two support through a contract to support RHCs in their implementation of COVID-19 testing capabilities for the detection, diagnosis, and treatment and reporting requirements. The RHCs are not typically funded by HRSA and will need support in meeting the reporting requirements.

### **Other Activities (\$8.3 billion)**

HHS continues to monitor the situation and support response and recovery activities supported with additional emergency supplemental resources. This funding will support COVID-19 responses efforts including the Administration's Testing Blueprint for Opening Up America

Again. The Plan's objectives are 1) Procurement and Distribution; 2) POC Diagnostics; 3) Serological Testing; 4) Community Based Testing; and 5) Building Future Capacity. The comprehensive HHS testing-related activities planned from this source are described below. This plan may evolve, and additional activities will be implemented, as HHS continues to identify the most efficacious means of supporting testing needs.

### 1 – Procurement and Distribution

- Remel Viral Transport Media (VTM)

Funding will help meet the increasing demands for testing capacity across states by providing specimen collection supplies including transport media. This activity complements the procurement of nasal swabs. To date, HHS has procured 32,623,800 transport media with these funds. Moving forward, HHS will procure 100 million Viral Transport Media tubes at a delivery rate of 3.85 million weekly to the Strategic National Stockpile for redistribution to the states.

- Puritan Swab Purchase

Funding will help meet the increasing demands for testing capacity across states by providing specimen collection supplies including swabs. This activity complements the procurement of nasal viral transport media. To date, HHS has procured 32,623,800 swabs with these funds. Moving forward, HHS will procure 100 million swabs (i.e. nasopharyngeal flocked, nasal foam tip, nasal spun polyester) to match the number of VTM being procured for the Strategic National Stockpile. Swabs shall be delivered at a rate of approximately 3.85 million weekly to the Strategic National Stockpile for redistribution to the states.

- ThermoFisher Extraction/PCR Kits

Funding will enable the procurement of 770 test kits that will allow HHS to perform 7 million diagnostic tests over the span of eight weeks. These kits include the reagents needed for both extraction of viral nucleic acid and amplification (PCR) and will enable states to maximize existing platforms.

### 2 – POC Diagnostics

- Quidel

Funding will enable the procurement of diagnostic technologies, including test instruments and tests, in order to facilitate an improved response. To this end, Quidel has recently received an Emergency Use Authorization from the FDA for the Sofia 2 SARS Antigen FIA, a rapid point-of-care test (results within 15 minutes) to be used with the Sofia 2 fluorescent immunoassay analyzer. The base install for the Sofia 2 is approximately 26,000 units nationally. Most of these units are located in provider and clinic settings. HHS will procure the SARS Antigen FIA and associated diagnostic platform for distribution to States and State Public Health Labs.

- Abbott ID Now Testing



Funding has supported the procurement of instruments and supplies for state rapid point-of-care testing. HHS will use additional funding to procure additional ID NOW tests, which be strategically distributed amongst the States, territories and tribes. This activity builds on initial ID Now test purchases (\$15 million) to provide rapid point-of-care testing for states.

### 3 – Serologic Testing

- Serological Survey Testing Pilots in NY and Detroit

Funding will support two serological pilots. HHS will collect a total of 140 thousand samples to examine the prevalence of COVID-19 antibodies among emergency health workers and first responders in New York City and Detroit.

- Serological Assays Funding will be used to procure serological assays that are capable of providing information on previous exposure and serological prevalence are key to the response. HHS will work to scale and procure rapid serological assays that can be utilized for determination of antibody prevalence and extent of previous exposure rates in specified geographies and high risk populations. Examples of these are health care workers including nursing home workers, first responders, workers in high risk industries where there have been outbreaks, and others. Data will be reported to CDC and incorporated into future models of disease transmission.

### 4 – Community Based Testing

- Community Based Testing Sites 3.0 Funding will pay for (fixed payment) the specimen collection fee for each COVID-19 test completed for up to a specific amount of tests. The specimen collection fee would include patient enrollment, patient testing, and patient notification. The purpose of this contract is to expand the availability of retail and pharmacy locations to increase testing capacity nationally by focusing on paying private retailers and pharmacies for specimen collection. This will allow for the maintenance and expansion of private retail and pharmacy locations throughout the United States.

### 5 – Building Future Capacity

- Scaling and Networking of Technologies

Funding for this program will be utilized to optimize the use of current technologies either through engineering automation or the development of hub and spoke networks. This initiative will be low risk and high reward by investing in demonstration projects that can immediately impact overall testing capabilities.

- Testing Demonstrations & Technical Assistance

Funding for this program will be utilized to utilize several mechanisms, including public-private-partnerships, to provide technical assistance to state, local and tribal governments to improve testing, surveillance and contact tracing programs.

Additional resources will be used to support additional COVID-19 responses efforts including expanding, accelerating, or initiating new testing efforts and capacity cross the Department.

These funds will also support the administration of programs identified by Congress including but not limited to allocating funding to states.

**HEALTH RESOURCES AND SERVICES ADMINISTRATION**  
**Fourth Coronavirus Preparedness and Response**  
**Supplemental Appropriations Act**  
**(Transfer)**

*(dollars in millions)*

Activity	Amount
Health Centers/1	600.00

1/ Funds were appropriated to the PHSSEF and directed for transfer to HRSA.

**Planned Activities**

Health center supplemental grant awards (\$583 million)

- Formula based, one-time supplemental grant awards to existing HRSA-funded health centers.
- Awards will support increased COVID-19 testing capabilities for the detection, diagnosis, and treatment of SARS-CoV-2. Supplemental awards are projected to support health centers to purchase, administer, and expand capacity to test and effectively monitor and suppress COVID-19.

Federally Qualified Health Center Look-alike Response and Capacity Grants (\$17 million)

- Formula based, one-time grant awards to existing eligible Federally Qualified Health Center (FQHC) Look-alikes.
- FQHC Look-alikes will be awarded funds to support increased COVID-19 testing capabilities for the detection, diagnosis, and treatment of SARS-CoV-2. These limited-competition awards will support eligible Look-alikes to purchase, administer, and expand capacity to test and effectively monitor and suppress COVID-19.



**CENTERS FOR DISEASE CONTROL AND PREVENTION**  
**Fourth Supplemental**  
**Paycheck Protection Program and Health Care Enhancement Act**  
**(Transfer)**

*(dollars in millions)*

Activity	Amount
Public Health Response and Capacity Building/1	\$1,000

1/ Funds were appropriated to the PHSSEF and directed for transfer to CDC.

HHS is closely coordinating across the Department to ensure that activities funded through the Paycheck Protection Program and Health Care Enhancement Act are complementary across programs, consider evolving factors associated with the novel Coronavirus and support the highest priority response activities to protect public health. This plan describes planned activities for a total of \$1.0 billion included in the Paycheck Protection Program and Health Care Enhancement Act, 2020.

**Planned Activities**

**Public Health Response and Capacity Building** (\$1 billion)

Through contracts, grants, and other mechanisms (e.g., salary and benefits, travel, equipment, supplies, telecommunications, etc.), CDC will:

- Further increase technical assistance for nationwide efforts in epidemiology and surveillance, laboratory capacity, and infection control.
- Build stronger laboratory capacity nationwide through support to the public health system, along with support for CDC’s core laboratory activities.
- Continue to develop tools and strategies, provide technical assistance and program support, as well as ensure ongoing communication and coordination among federal, state, local, tribal, and territorial public health agencies and partners throughout the response.
- Leverage data for surveillance, detection, and improving state and local jurisdictions’ situational awareness, which will allow for localized and targeted responses and decision-making using more real-time data.
- Expand the electronic exchange and integration of information between public health and health care, including electronic health records, which is essential for timely, accurate, and accessible disease surveillance.
- Increase support for public health data science, informatics, and advancing interoperable systems and tools.

Note: Working Capital Fund and program support costs will be spread across activities.

**NATIONAL INSTITUTES OF HEALTH**  
**Fourth Supplemental**  
**Paycheck Protection Program and Health Care Enhancement Act**  
**(Transfer)**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
RADx Advanced Testing Program (RADx-ATP)	230.00
RADx Radical (RADx-Rad)	200.00
RADx-Underrepresented Populations (RADx-UP)	500.00
Data Management for Testing for Safe Release	70.00
<b>Subtotal, Office of the Director Coronavirus Funding</b>	<b>1,000.00</b>
RADx Fast-track Innovation Funnel (RADx-Tech)	500.00
<b>Subtotal, NIBIB Coronavirus Funding</b>	<b>500.00</b>
Serology and Immunology Capacity Building	98.00
Clinical Serological Sciences	73.00
Foundational Serological Sciences	135.00
<b>Subtotal, NCI Coronavirus Funding</b>	<b>306.00</b>
<b>Total, NIH Coronavirus Funding/1</b>	<b>1,806.00</b>

1/ Funds were appropriated to the PHSSEF and directed for transfer to NIH.

The National Institutes of Health (NIH) will respond to the COVID-19 outbreak by speeding innovation, development and commercialization, and implementation of COVID-19 testing through the Rapid Acceleration of Diagnostics (RADx) initiative. RADx will infuse funding into early innovative technologies, including those using non-traditional approaches, to speed development of rapid and widely accessible COVID-19 testing. At the same time, NIH will seek opportunities to move more advanced diagnostic technologies swiftly through the development pipeline toward commercialization and broad availability. Efforts will also be undertaken to expand the testing infrastructure across the country by investigating, in real-time, a variety of testing methods/approaches to better understand the uptake, administration, and effectiveness in specific populations, areas, or settings. NIH will work closely with other agencies, including the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority (BARDA), to advance these goals.

As part of this initiative, the National Institute of Biomedical Imaging and Bioengineering (NIBIB) will support efforts across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public's safe return to normal activities. The technologies will be put through a highly competitive, accelerated three-phase selection process to identify the best candidates for at-home or point-of-care tests for COVID-19. The RADx fast-track innovation funnel (RADx-Tech) will leverage the structure and resources of the NIH Point-of-Care Technology Research Network (POCTRN) established several years ago by NIBIB. Finalists will be matched with technical, business and manufacturing experts to increase the odds of success. Selected technologies that are already relatively far along in development can be put on a separate track and be immediately advanced to the appropriate step in the commercialization process.

The Office of the Director (OD) will sponsor four projects:

- The RADx-Underrepresented Populations (RADx-UP) Project will be a series of interlinked community-based demonstration projects focused on evidence-based implementation strategies to enable and enhance testing of COVID-19 in underserved, under-resourced, rural, and/or vulnerable populations and address the unique needs of the different communities.
- The RADx Radical (RADx-Rad) Project will develop and advance novel, non-traditional approaches or new applications of existing approaches for testing, including unconventional screening, biological or physiological markers, new platforms, and point-of-care devices.
- The RADx Advanced Testing Program (RADx-ATP) Project will support the scale-up of advanced technologies to increase rapidity and enhance and validate throughput, including creation of ultra-high throughput machines and facilities.
- The Data Management for Testing for Safe Release Project will build an infrastructure for the various data management needs such as a platform to integrate data from a variety of sources, including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and electronic health records data.

In addition to the RADx initiative, the National Cancer Institute (NCI) will use its expertise in serology to address the critical national need for reliable, widely available COVID-19 serological testing in response to the current pandemic. This effort will include support for three research activities: Serology and Immunology Capacity Building, Clinical Serological Sciences, and Foundational Serological Sciences.

HHS is closely coordinating across the Department to ensure that activities funded through the Coronavirus Aid, Relief, and Economic Security Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes planned activities for a total of \$1,806.0 million included for NIH in the Paycheck Protection Program and Health Care Enhancement Act.

**Office of the Director, National Institutes of Health  
Paycheck Protection Program and Health Care Enhancement Act  
(Transfer)**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
RADx Advanced Testing Program (RADx-ATP)	230.00
RADx Radical (RADx-Rad)	200.00
RADx-Underrepresented Populations (RADx-UP)	500.00
Data Management for Testing for Safe Release	70.00
<b>TOTAL</b>	<b>1,000.00</b>

The Office of the Director, National Institutes of Health, will support efforts aimed at speeding innovation, development and commercialization of COVID-19 testing through the Rapid Acceleration of Diagnostics (RADx) initiative, which also includes the National Institute of Biomedical Imaging and Bioengineering (NIBIB) fast-track innovation funnel (RADx-Tech). NIH will work closely with other agencies, including the U.S. Food and Drug Administration, the Centers for Disease Control and Prevention and the Biomedical Advanced Research and Development Authority (BARDA), to advance these goals.

This plan describes planned activities for a total of \$1 billion included for the Office of the Director in the Paycheck Protection Program and Health Care Enhancement Act.

**Planned Activities**

RADx Advanced Testing Program (RADx-ATP) (\$230 million)

- This effort will identify diagnostic testing approaches for COVID-19 that are currently far enough advanced that rapid scale-up can be achieved in a reasonably short period of time to address the pandemic in real-time. These efforts will focus on scaling up existing technologies to increase rapidity and enhance and validate through-put, including the creation of ultra-high throughput machines and facilities. Engineering innovations can be introduced to existing high-throughput machines to increase analytical and operational performance. Potential approaches could include scaling up testing and utilization through large capacity regional testing hubs that leverage large NIH clinical networks such as CTSA's and Cancer Centers.
- Each of these approaches would require optimization and certification (*e.g.*, Clinical Laboratory Improvement Amendments (CLIA)), but also have different throughput per machine and different technical specs matched to use cases.
- This effort will utilize both Other Transactions Authority and contracts.
- Specific project examples may include:
  - Build on/leverage Point of Care Technology Research Network (POCTRN) capabilities to validate and perform clinical tests and obtain needed regulatory approvals. This approach would leverage existing companies to create solutions that target and reach certain design specifications and offer diverse challenges to rapidly advance and/or scale testing capacity across the country.

- Development of modular test panels for multiple infectious diseases (differential diagnosis), including viral agent and the immune response, bacteria, genetics, other syndromes.

#### RADx Radical (RADx-Rad) (\$200 million)

- This effort will support novel concepts that address current gaps in SARS-CoV-2 testing through non-traditional approaches. This effort will focus on non-traditional viral screening approaches, such as biological or physiological markers, new analytical platforms with novel chemistries or engineering, rapid detection schemes, point-of-care devices, and home-based testing technologies. In addition, novel or non-traditional applications of existing approaches to enhance usability, access, robustness, or accuracy will be encouraged. These ideas may take a bit longer to actualize, but could provide novel approaches, such as breath or wastewater analysis, to identify the SARS-CoV-2 virus and may be applicable to other, as yet unknown, viruses.
- This effort will utilize grant mechanisms.
- Specific project examples may include:
  - Modular approaches that could be developed over the longer-term would include those that allow rapid response to diagnostic needs now and in future outbreaks, including the development of revolutionary new approaches both in chemistries (*e.g.*, CRISPR), fluidics (*e.g.*, microfluidic chips, parallel processing nanodroplets), detection schemes (*e.g.*, cell phones/integrated opto-electronics, ASICs), biomarkers (*e.g.*, combination of biomarkers that can predict severity of disease), surveillance (*e.g.*, population- or community-level testing data to indicate prevalence), and sampling (*e.g.*, exhaled breath, saliva). These approaches represent solutions to be deployed either now and/or in the future, potentially giving a more modular toolbox for “mixing and matching” components according to diagnostic needs.

#### RADx-Underserved Populations (RADx-UP) (\$500 million)

- This effort represents an opportunity to develop an infrastructure to assess and expand evidence-based testing interventions and capacity for those populations that are disproportionately affected by, have the highest infection rates of, and/or are most at risk for adverse outcomes from contracting the virus.
- It will establish a series of interlinked community-based demonstration project(s) focused on implementation strategies to enable and enhance testing of underserved, under-resourced, rural, and/or vulnerable populations (*e.g.*, underrepresented minorities, nursing homes, homeless, underlying conditions, pregnant women, jails) across the United States.
- This effort will utilize a combination of Other Transactions Authority (OTA), contracts, and grant mechanisms.
- Specific activities may include the following in order to focus on novel development or application of existing devices for use in rural and/or underserved/under-resourced communities:
  - It will establish pragmatic clinical trials at multiple sites across the country to investigate, in real-time, a variety of testing methods/approaches to better understand the uptake, administration, and effectiveness in specific populations, areas, or settings.



- Sites within this initiative will partner with community health centers (*e.g.*, Tribal health centers, HRSA community health centers, federally qualified health centers), houses of worship, homeless shelters, and prison systems to identify and address the unique needs of the different communities.
- This initiative will leverage the advances brought forth from the RADx efforts and develop testing strategies to use them in real-world settings, such as distribution of at-home diagnostic kits.
- Given the expected rapid expansion of vaccine trials and the need for associated serological and other testing strategies, this demonstration project will serve as a resource for more routine testing once the vaccine trials accelerate.
- An ethical-legal-social implications (ELSI) program will be built into this initiative to understand the range of ELSI issues associated with testing/diagnostic technologies and information/data (including stigma associated with a positive test result) in research, clinical, or other settings.

#### Data Management for Testing for Safe Release (\$70 million)

- The Data Management for Testing for Safe Release Project will build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts. A primary initial focus will be on the development of a platform to integrate data, on individuals and populations, from a variety of sources, including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and EHR data. The platform will report deidentified information to ensure the privacy of individuals. It will also provide a resource of indexed and searchable data and incorporate some analytics tools. Deidentified data will be made publicly available to researchers through standard controlled access procedures.
- This initiative will leverage coordinated efforts with the CDC to include data from the National Death Index and health claims data.
- This effort anticipates making approximately 10 awards using a hub and spoke model. The goal is to incorporate data from tens of thousands of people (~50,000) initially and exponentially increase to hundreds of thousands of people (~500,000) within a rapid timescale (months).
- This effort will utilize a combination of Other Transactions Authority (OTA) and contracts.

**National Institute of Biomedical Imaging and Bioengineering  
Paycheck Protection Program and Health Care Enhancement Act  
(Transfer)**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
RADx Fast-track Innovation Funnel (RADx-Tech)	500.00
<b>Total, NIBIB Coronavirus Funding</b>	<b>500.00</b>

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) will support efforts across multiple projects to rapidly produce innovative SARS-CoV-2 diagnostic tests that will assist the public’s safe return to normal activities. The Rapid Acceleration of Diagnostics (RADx) fast-track innovation funnel (RADx-Tech) will leverage the structure and resources of the National Institutes of Health (NIH) Point-of-Care Technology Research Network ([POCTRN](#)). RADx-Tech will support solutions that build the U.S. capacity for SARS-CoV-2 testing up to 100-fold above what is achievable with standard approaches. The RADx-Tech is structured to deliver innovative testing strategies to the public as soon as late summer 2020 and is an accelerated and comprehensive multi-pronged effort by NIH to make SARS-CoV-2 testing readily available to every American.

NIH is conducting this program in close collaboration with BARDA, sharing information and resources to insure complementarity and best use of funds at both agencies. Members of the FDA serve on RADx-Tech advisory boards and are involved in the ongoing governmental oversight of projects as they move through the developmental pipeline to prepare for and streamline FDA approval of successful devices. As many of the RADx-Tech proposals are coming from small businesses and academic institutions, partnerships with large manufacturers and distributors will be critical for rapid public access to new tests. One important role for BARDA is to facilitate partnerships with large companies.

This plan describes planned activities for a total of \$500 million included for NIBIB in the Paycheck Protection Program and Health Care Enhancement Act.

**Planned Activities**

The RADx-Tech is structured to provide escalating support to awardees in a stage-gated manner, although more advanced proposals may be able to skip a stage. RADx-Tech has assembled a national network of expert technical, clinical, regulatory and commercialization advisors who will provide individualized assistance for project development and commercialization. Proposals submitted to the RADx-Tech undergo a rigorous multistage review process. Proposals are reviewed by an external panel of experts for technical, clinical, regulatory, and commercialization feasibility based on the Project Review Criteria stated in the solicitation. With NIH approval, the most promising projects then enter the Phase 0 “deep dive” process, an up to two-week process during which experts conduct an intensive review with the submitters to carefully examine all aspects of the project and identify potentials risks to development and deployment. Following the deep dive, the subset of projects that are deemed most promising and feasible for rapid development can move to either phase 1 or, for projects that are at an advanced stage, directly to phase 2. Projects are funded incrementally based on accomplishment of key

derisking milestones that are established during the deep dive. At each milestone, experts review progress and assess feasibility before the project is allowed to continue in RADx-Tech. For successful projects, NIBIB will provide financial and in-kind support to accelerate the entire product life cycle, from design to market, for projects that meet aggressive milestones successfully. A small portion of program funding will be used for administrative costs, up to five percent.

#### RADx-Tech Phase 0

- Approximately 100-150 successful applicants will receive \$25,000 contract awards to enter into the Phase 0 “Shark-Tank”-like rapid selection process. Contracts through Biocomx and VentureWell will provide administrative support to facilitate and expand proposal review, project management and award-making throughput. These contracts will support activities throughout all program phases. Proposals will be accepted on a rolling basis beginning April 29, 2020. Proposals will be reviewed by an external expert panel for program suitability and technology readiness level.
- Selected projects will be assigned a team of content and commercialization experts to do a “deep dive” with the applicant. This process will identify key risk factors that may impede the rapid deployment of the proposed solution, as well as clear milestones that address such risks. Depending on the maturity of the project, the process will take from a few days to two weeks.

#### RADx-Tech Phase 1

- Approximately 20 projects will be selected for progression to Phase 1. The estimated award amount for these projects is \$500,000 to \$1 million. More advanced approaches with higher technology readiness levels could be selected for acceleration directly to Phase 2. NIH will make the final determination about which projects are accepted into each phase. Funding for Phase 1 will be provided as administrative supplements to the POCTRN Centers Cooperative Agreement awards.
- In addition to financial resources, project teams will be provided with expert advisors and in-kind technical, clinical, manufacturing, and regulatory support. These experts will identify defined risks for each project and establish milestones accomplishments needed to mitigate these risks. Risks may be missing supporting data, such as validation with clinical samples, the need to meet sensitivity and specificity targets, or may involve practical challenges such as the supply chain. As appropriate to the risks identified in the projects, Phase 1 funding disbursement may be dependent on successful accomplishment of quantitative, pre-specified milestones throughout the ~4-week period of Phase 1. NIH approval is required for milestone payments during Phase 1.

#### RADx-Tech Phase 2

- Approximately 5-10 projects will be selected from those that complete Phase 1 milestones or enter straight from Phase 0. Depending on the work needed to ready a specific test for distribution, costs may vary widely from approximately \$10 million to \$60 million and may involve a combination of direct monetary awards and access to service contracts, e.g., for scale up and manufacturing. NIH will establish direct funding mechanisms via contracts or Other Transactions Authority.

- This phase will include scale-up and manufacturing to fully deploy tests to the public on the shortest possible timeline. NIH aims to produce approximately five successful testing approaches to result from this program that, in combination, will deliver tens of millions of tests per week. The RADx-Tech expert consulting team will continue to support the projects, and NIH will negotiate cost sharing with for-profit institutions as appropriate. Milestones that define key de-risking steps will determine whether project funding will continue during Phase 2. NIH will evaluate progress at each milestone and make incremental funding decisions based on project progress. Phase 2 funding may span 3-12 months, depending on the stage of development of the project technology.

**National Cancer Institute  
Paycheck Protection Program and Health Care Enhancement Act  
(Transfer)**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
Serology and Immunology Capacity Building	98.00
Clinical Serological Sciences	73.00
Foundational Serological Sciences	135.00
<b>Total, NCI Coronavirus Funding</b>	<b>306.00</b>

The National Cancer Institute (NCI) will use its expertise in serology to address the critical national need for reliable, widely available COVID-19 serological testing in response to the current pandemic. This effort will include support for three research activities described below.

This plan describes planned activities for a total of \$306 million included for NCI in the Paycheck Protection Program and Health Care Enhancement Act.

**Planned Activities**

Serology and Immunology Capacity Building (\$98 million)

- Evaluation of Commercially Available COVID-19 Serology Tests on behalf of FDA – With the expertise of the HPV (Human Papilloma Virus) Serology Lab, part of the Frederick National Laboratory for Cancer Research, NCI is supporting the evaluation of commercially available COVID-19 serology tests and is reporting performance data on these to the FDA.
  - This activity will be supported by contract with the Frederick National Laboratory for Cancer Research
- Serology and Immunology Capacity Building Centers – NCI and the National Institute of Allergy and Infectious Diseases (NIAID) will establish a collaborative national network to develop serological assays of high specificity and sensitivity for rapid deployment to test for SARS-CoV-2 induced immune responses. This network will increase national capacity for high-quality serological testing with return-of-results to subjects and will also support related clinical efforts including clinical trials of convalescent serum and creating registries of tested subjects for sero-protection studies.
  - This activity will be supported by an existing contract with the Frederick National Laboratory for Cancer Research and a series of awards (through a combination of new competitive grants, contracts, and/or administrative supplements to existing grants). It is anticipated that academic medical institutions and small companies are likely to respond and compete favorably.
- Information Technology Development for Application of Serologic Results – In collaboration with NIAID and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), NCI will develop necessary IT support to understand the meaning and utility of COVID-19 serologic status.
  - This activity will be supported by competitive contracts to qualified academic entities and companies, with priority given to small businesses.

### Clinical Serological Sciences (\$73 million)

- NCI COVID-19 in Cancer Patients Study (N-CCaPS) – Starting in mid-May 2020, this clinical trial will investigate the natural history of COVID-19 infection in cancer patients, research how cancer treatment outcomes are impacted by COVID-19 infection, provide samples for the assessment of the role of germline genetics in COVID-19 outcome, and assess long term effects of COVID-19 on cancer outcomes and quality of life. This study will accrue 2000 patients nationwide by 12/1/2020 and will complete follow up by the end of 2021.
  - This activity will be supported through a series of awards (through a combination of new competitive grants, contracts, and/or administrative supplements to existing grants). These awards will most likely be directed to NCI designated cancer centers and clinical trials networks (*e.g.*, NCTN and NCORP).
- COVID-19 Cancer Consortium – This collaboration between NCI and the NCI designated cancer centers will collect clinical data on cancer patients with COVID-19 and identify and evaluate ways to safely re-start preventive cancer screenings and other care as clinics gradually re-open.
  - This activity will be supported through competitive grant supplements to NCI designated cancer centers.
- Serological surveys and sero-protection studies – Working with NIAID, the NCI will provide support to academic entities to perform serological testing in specific populations (*e.g.*, health care workers, vulnerable populations, under-represented minority populations) and to support longitudinal studies of the COVID-19 ‘attack rate’ in seropositive versus seronegative individuals.
  - This activity will be supported through a series of awards (through a combination of new competitive grants, contracts, and/or administrative supplements to existing grants). These awards will most likely be directed to NCI designated cancer centers and other institutions awarded competitive applications.

### Foundational Serological Sciences (\$135 million)

- Serological Sciences Centers of Excellence – NCI and NIAID will establish a collaborative national network focusing on characterizing the immune responses elicited by coronavirus infection, understanding the mechanisms driving the serological, humoral and cellular immune responses, and determining the serological correlates with disease pathogenesis and protection against future infection. This network will interact with the capacity building centers administered through the Frederick National Laboratory for Cancer Research.
  - This network will be established through grants to institutions responding to the Request for Applications which will be posted in June.

**OFFICE OF INSPECTOR GENERAL**  
**Fourth Supplemental**  
**Paycheck Protection Program and Health Care Enhancement Act**  
**(Transfer)**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
OIG Oversight PPP Extension Funding /1	6.00

1/ Funds were appropriated to the PHSSEF and directed for transfer to OIG.

**Planned Activities**

**OIG Oversight** (\$6 million)

A total of \$6 million will support the Office of Inspector General (OIG) to oversee HHS efforts to combat COVID-19. OIG reviews will help ensure proper oversight and management by HHS agencies, including oversight of the emergency supplemental funding provided to HHS's Operating Divisions and oversight of health and human services combatting or impacted by COVID-19. This would include assessing the efficiency and effectiveness of HHS activities, grants, contracts, and providers. It would include assessing internal controls and procedures for ensuring the safety and provision of necessary resources to individuals or entities impacted by COVID-19.

**FOOD AND DRUG ADMINISTRATION**  
**Fourth Supplemental**  
**Paycheck Protection Program and Health Care Enhancement Act**  
**(Transfer)**

*(dollars in millions)*

<b>Activity</b>	<b>Amount</b>
FDA (CDRH) COVID-19 Testing Personnel (FY2020-FY2024)	\$21.60
Testing Sample Panels for Emergency Use Authorizations (EUAs)	\$0.40
<b>Total, HHS, Coronavirus Funding/1</b>	<b>\$22.00</b>

1/ Funds were appropriated to the PHSSEF and directed for transfer to FDA.

HHS is closely coordinating across the Department to ensure that activities funded through the Paycheck Protection Program and Health Care Enhancement Act are complementary across programs, consider evolving factors associated with the Coronavirus, and support the highest priority response activities to protect public health.

This plan describes activities for a total of \$22.0 million included for the Food and Drug Administration (FDA) in the Paycheck Protection Program and Health Care Enhancement Act.

**Planned Activities**

**Fortifying Related Personnel Support to Maximize Effectiveness and Flexibility for US COVID-19 Testing (\$21.60 million)**

- The work performed by FDA personnel will include:
  - Review of COVID-19 diagnostic tests, prioritizing review of manufacturers and test developers.
  - Supporting development of reference materials and standards to assess diagnostic products.
  - Reducing the amount of time, it takes to review COVID-related submissions.
  - Specialized training related to COVID-19 response.

FDA anticipates utilizing Title 42 Hiring Authority to hire temporary FTE, including Molecular Biologists, Microbiologists, Medical Technologists, an Infectious Disease Doctor, and Policy Analysts.

**Sample Panel and Reference Material Development for EUAs (\$0.40 million)**

- FDA will work with other government entities to develop sample panels and reference materials to accelerate the development and testing of diagnostic tests.
- Costs include travel, purchasing of sample specimens, and other miscellaneous expenses.