



■ FOR LEARNING ■ FOR LISTENING ■ FOR LIFE

Federal Response to the Coronavirus Pandemic

Introduction

The following is a resource for members of the Association of Clinical Research Professional (ACRP) detailing the key federal initiatives and policies that you should be aware of during this coronavirus (COVID-19) pandemic.

On March 6, 2020, President Trump signed the **Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R.6074), (Public Law No: 116-123)** into law. This Act provided \$8.3 billion in emergency funding for federal agencies to respond initially to the coronavirus outbreak. The full text and a summary of the provisions within H.R.6074 can be found [here](#).

On March 18, 2020, President Trump signed the **Families First Coronavirus Response Act (H.R.6201), (Public Law No: 116-127)** into law. This Act responds to the coronavirus disease outbreak by providing paid sick leave, tax credits, and free testing; expanding food assistance and unemployment benefits; and increasing Medicaid funding. The full text and a summary of the provision within H.R.6201 can be found [here](#).

On March 27, 2020, President Trump signed the **Coronavirus Aid, Relief, and Economic Security Act (the Cares Act) (H.R.748)** into law. The Act provides relief \$2 trillion in funding to address the needs of individuals and employers, states, and health care providers dealing with the fallout from the pandemic. The full text and a summary of the provision within H.R.748 can be found [here](#).

Key Provisions for ACRP Members:

While many parts of these new coronavirus related laws will be of interest, we have identified key elements that ACRP members should be familiar with. Details on these elements are provided below. The Departments of Treasury, Labor, and Health and Human Services will be issuing guidance on various parts of these laws and ACRP will keep you updated on these announcements and their impact on members.

Biomedical Advanced Research and Development Authority

The bill allows the Biomedical Advanced Research and Development Authority (BARDA) to partner with private sector companies on research and development by removing the cap on BARDA's other transaction authority (OTA) during a public health emergency. (Under current law BARDA is authorized to take away a company's patent exclusivity rights, which allows other applicants to develop an otherwise patented drug. The bill enables more of a partnership in drug development but could also undercut the government's ability to act if a drug, such as a COVID-19 vaccine, is priced too high.)

The measure allows the FDA to provide "breakthrough therapy" designations for animal drugs that help prevent animal-to-human transmission.

Defense Health Programs

The total includes \$3.8 billion for the Defense Health Program — which provides medical care to military personnel, including active duty troops and their dependents — and \$1.1 billion for Tricare, the insurance program that oversees military health care benefits, including those for Medicare-eligible military retirees and their families.

It includes \$1.6 billion for expansion of military hospitals and expeditionary hospital packages, allowing the department to nearly triple the 4,300 beds available in military treatment facilities today.

It also includes \$415 million for research and development of vaccines and anti-viral pharmaceuticals and the procurement of diagnostic tests.

National Institutes of Health

The measure provides \$946 million to the National Institutes of Health (NIH) for vaccine, therapeutic and diagnostic research.

Public Health and Social Services Emergency Fund

H.R.748 provides funding of \$100 billion to the Department of Health and Human Services 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. "Eligible health care providers" means public entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit entities and not for-profit entities the Secretary may specify, within the United States that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID-19.

Funds shall also be available for building or construction of temporary structures, leasing of properties, medical supplies and equipment including personal protective equipment and testing supplies, increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity.

Other agencies including the Department of Homeland Security have also been provided resources to secure personal protective equipment.

Hospital Aid through Medicare

H.R.748 temporarily lifts the Medicare sequester, which reduces payments to health care providers by 2%. The sequester is lifted from May 1 through Dec. 31, 2020. To make up for the increased payments to providers, the sequester is extended by one year beyond current law. It increases by 20% the payment that hospitals receive from Medicare for treating a patient with COVID-19. The additional payment would be made through the duration of the COVID-19 public health emergency.

It allows qualified hospitals to request an advance lump sum or periodic payment of up to six months under the existing Medicare accelerated payment program. The amount would be based

on net reimbursement and most hospitals could receive up to 100% of prior period payments, while critical access hospitals could receive up to 125%. These payments are considered loans.

Under the measure, qualifying hospitals would not have to start repaying the loan for four months and would have at least 12 months interest free to complete repayment.

Under the measure, during the COVID-19 emergency acute care hospitals would be allowed to transfer patients to alternative care settings in order to prioritize resources needed to treat COVID-19 cases. Specifically, the measure waives the existing Inpatient Rehabilitation Facility (IRF) three-hour rule, which requires a beneficiary to participate in at least three hours of intensive rehabilitation at least five days per week to be admitted to an IRF. It also allows a long-term care hospital (LTCH) to maintain that designation even if more than 50% of its cases are less intensive. In addition, the measure temporarily pauses the current LTCH site-neutral payment methodology.

The bill prevents the scheduled reductions in Medicare payments for clinical diagnostic laboratory tests furnished to beneficiaries in 2021. It also delays for one year the upcoming reporting period during which laboratories would report private payer data.

Hospital Aid through Medicaid

The bill amends a section of the Families First Coronavirus Response Act of 2020 to ensure that states are able to receive the Medicaid 6.2% Federal Medical Assistance Percentage (FMAP) increase.

Finally, the bill clarifies that uninsured individuals can receive COVID-19 testing and related services with no cost sharing in any state Medicaid program that elects to offer that option.

Rectify Supply Shortages

The bill includes provisions that are meant to address current shortages of personal protective equipment and medical devices. It expands the list of medical supplies the Strategic National Stockpile can stockpile, including swabs for diagnostic testing for COVID-19, personal protective equipment, other supplies required for administering drugs and vaccines, and diagnostic tests.

It makes permanent the current liability protection granted to manufacturers of personal respiratory protective equipment whose equipment meets National Institute for Occupational Safety and Health (NIOSH) standards rather than Food and Drug Administration (FDA) standards. Specifically, those protections are granted in times of public health emergencies, to incentivize manufacturers to produce and distribute their protective equipment to health care providers.

During a public health emergency, medical device manufacturers would be required, upon request by the FDA, to submit information about medical device shortages or device component shortages.

Under the measure, the FDA must prioritize and expedite the review of drug applications and inspections that are necessary to prevent or mitigate a drug shortage.

The bill expands existing reporting requiring for drug manufacturers in response to the shortage of a critical drug during a public health emergency. Specifically, if there is an interruption in the

supply of a critical drug, manufacturers must submit additional information to the FDA, including information about the active pharmaceutical ingredients, when those ingredients are the cause of the interruption. Manufacturers must maintain contingency plans to ensure a backup supply of products. Drug manufacturers must provide information regarding any drug registered with the FDA regarding how much was manufactured for commercial distribution each year.

Health Care Workforce Programs

Specifically, H.R.748 reauthorizes through FY 2025 a number of health professions workforce programs and authorizes annual appropriations in the following amounts: \$24 million for health profession schools that have been designated as Centers of Excellence; \$51 million for health education scholarships; \$1 million for loan repayments and fellowships; \$15 million for educational assistance in health professions for individuals from disadvantaged backgrounds; \$49 million for primary care training programs; \$29 million for general, pediatric, and public health dentistry; \$41 million for area health education centers; \$6 million for health professions workforce information and analysis; and \$17 million for the public health workforce.

It also requires HHS to develop a comprehensive and coordinated plan for health care workforce development programs, including education and training programs. The plan should include performance measures and identify gaps between the outcomes of development programs and workforce projection needs.

Finally, it modifies the requirements for receiving grants under the geriatric education center program to emphasize patient and family engagement, integration of geriatrics with primary care and other appropriate specialties, and collaboration with community partnerships to address gaps in health care for older adults.

Nursing Workforce Development

The bill reauthorizes Title VIII of the Public Health Service Act, which deals with programs to support nurse workforce training.

Specifically, it reauthorizes through 2025 and authorizes annual appropriations of \$138 million for nurse practitioners, nurse midwives, nurse anesthetists, and other advanced education nurses; nurse workforce diversity; and basic nurse education and practice. It also authorizes annual appropriations of \$117 million through FY 2025 for repaying nursing student loans and permits Nurse Corps loan repayment beneficiaries to serve at private institutions under certain circumstances.

HRSA Grant Programs including Telehealth Grants

The measure reauthorizes HRSA grant programs for telehealth, rural health care, and small health care providers.

Specifically, the bill authorizes \$29 million annually through FY 2025 for grants to promote the use of telehealth technologies for health care delivery, education and health information. It adds substance use disorder to the health issues for which telehealth can be developed and used and stipulates that at least 50% of the funds must be awarded for projects in rural areas.

It authorizes \$80 million annually through FY 2025 for grants to strengthen rural community health by focusing on quality improvement, increased access, coordination of care, and

integration of services. Grants can be awarded for a maximum of five years.

Other Health Care Workforce Provisions

The bill clarifies that the existing Ready Reserve Corps can be called up in time of a public health or national emergency to bolster the number of trained doctors and nurses available to respond to the crisis. It provides liability protections for health professionals who volunteer their medical services during the COVID-19 public health emergency.

Under the measure, HHS is authorized to reassign members of the National Health Service Corps to sites close to where they were originally assigned in order to respond to the current health emergency. The corps member must agree to the reassignment.

Health Care for COVID-19 Patients

The bill requires that all testing for COVID-19 be covered by private insurance plans and that patients cannot be charged a copay or a deductible for the test. This includes tests for which the FDA has not yet approved the test developer's emergency use application, as long as the application has not been denied and as long as the developer submits an application within a reasonable time.

Health insurance companies would pay health care providers for the COVID-19 tests at the rate specified in a contract between the insurer and the provider. If there is no contract, the insurance company would pay the provider's posted cash price. The bill requires health care providers to publicly post on their websites their cash prices for testing.

Once a COVID-19 vaccine with an A or B rating in the current recommendations of the United States Preventive Services Task Force or a recommendation from the Advisory Committee on Immunization Practices has been developed, private health insurance plans must cover the vaccine for their enrollees free of charge.

For plan years beginning on or before Dec. 31, 2021, the bill allows high-deductible health plans with health savings accounts (HSAs) to cover telehealth services prior to a patient reaching the deductible.

HHS Extenders

It extends through Nov. 30 funding for the following HHS programs, most of which expire on May 22: quality measure endorsement and selection, outreach and assistance for low-income programs, Medicaid's money follows the person demonstration program, spousal impoverishment protections, Medicaid community mental health services demonstration, sexual risk avoidance education, personal responsibility education, health professions opportunity grants, TANF and related programs, Community Health Centers, the National Health Service Corps, the Teaching Health Center Graduate Medical Education Program, and the Special Diabetes Program for Type I Diabetes and the Special Diabetes Program for Indians.

It also delays scheduled reductions in Medicaid disproportionate share hospital payments through Nov. 30, 2020.

New Paid Sick Leave and Family and Medical Leave Benefits

A significant part of H.R.6201 establishes paid sick leave and expanded family and medical leave

benefits for workers. The U.S. Department of Labor's Wage and Hour Administration administers the programs and issues guidance to employers and employees. Please check this link regularly for guidance updates.

<https://www.dol.gov/coronavirus>

<https://www.dol.gov/agencies/whd/pandemic/ffcra-questions>

The Act provides that employees of covered employers are eligible for:

- Two weeks (up to 80 hours) of **paid sick leave** at the employee's regular rate of pay where the employee is unable to work because the employee is quarantined (pursuant to Federal, State, or local government order or advice of a health care provider), and/or experiencing COVID-19 symptoms and seeking a medical diagnosis; or
- Two weeks (up to 80 hours) of **paid sick leave** at two-thirds the employee's regular rate of pay because the employee is unable to work because of a bona fide need to care for an individual subject to quarantine (pursuant to Federal, State, or local government order or advice of a health care provider), or to care for a child (under 18 years of age) whose school or child care provider is closed or unavailable for reasons related to COVID-19, and/or the employee is experiencing a substantially similar condition as specified by the Secretary of Health and Human Services, in consultation with the Secretaries of the Treasury and Labor; and
- Up to an additional 10 weeks of **paid expanded family and medical leave** at two-thirds the employee's regular rate of pay where an employee, who has been employed for at least 30 calendar days, is unable to work due to a bona fide need for leave to care for a child whose school or child care provider is closed or unavailable for reasons related to COVID-19.

The paid sick leave and expanded family and medical leave provisions apply to certain public employers, and private employers with fewer than 500 employees. Small businesses with fewer than 50 employees may qualify for exemption from the requirement to provide leave due to school closings or childcare unavailability if the leave requirements would jeopardize the viability of the business as a going concern.

The Secretary of Labor has the authority to exclude certain health care providers and emergency responders from the definition of employee under these new benefits by allowing the employer of such health care providers and emergency responders to opt out. Further guidance from the Department of Labor is expected on this shortly.

Rather than being permanent, the program is set to expire Dec. 31, 2020.

New Unemployment Benefits

Under current law, unemployment insurance is available to individuals who have lost their jobs, and UI benefits replace part of their wages while they look for work. States run the basic unemployment insurance program, and most replace about half of an individual's wages for up to 26 weeks. A second program, the permanent extended benefits program, provides an additional 13 to 20 weeks of compensation once regular benefits have been exhausted, but only in states where the unemployment situation has gotten dramatically worse. Usually, states and the federal government split the cost of extended benefits.

H.R.6201 temporarily expands UI benefits for the millions who are losing their jobs because of

the coronavirus pandemic, with the federal government picking up the cost through a Federal Pandemic Unemployment Compensation program — including by providing for immediate benefits, providing an additional \$600 per week through July, and providing for an additional 13 weeks of regular benefits beyond the normal 26 weeks. It also generally expands eligibility for UI benefits to individuals who currently cannot receive traditional UI, including the self-employed, independent contractors, "gig" workers and others with limited work histories.

Under the measure, the expanded UI benefits would be available to workers who are unemployed due to a wide variety of effects of the coronavirus, including: their own illness, illness in a family member, the necessity to quarantine, job loss because of the virus, and staying home to take care of a child whose school or child care is closed because of the virus. It explicitly excludes those who can telework for pay, or who are already receiving paid sick leave or other paid leave benefits.

The bill's UI expansions would expire at the end of calendar year 2020, and state participation in the expanded program would be voluntary.

[Guide for Filing for Unemployment](#)

Short-Time Compensation Payments

Short-Time Compensation (STC) programs, also known as work sharing or shared work programs, are a variation of unemployment insurance meant to prevent layoffs. Under such programs, instead of laying off workers during an economic downturn, employers can cut back the number of hours worked and spread those hours among the entire workforce — with workers whose hours are cut receiving a prorated UI benefit to make their compensation whole. Not all states have STC programs.

Under H.R.6201, the federal government would pay 100% of a state's STC benefits, for up to 26 weeks of benefits for states that already have, or that establish, permanent programs in 2020. For states that establish temporary STC benefit programs, the federal government would pay up to 50% of the state's benefit costs. Federal funding for both permanent and temporary programs would end Dec. 31, 2020, and individuals employed on a seasonal, temporary or intermittent basis would not be eligible for federal funding under state STC programs.

Refundable Tax Credit to Assist Employers with Paid Sick Leave and FLMA Benefits

To defray the costs of these new employee benefits during this pandemic, employers would receive a 100 percent refundable tax credit applied to the employer portion of the Social Security payroll tax for both paid sick leave and family leave wages.

Eligible employers who pay qualifying sick or childcare leave will be able to retain an amount of the payroll taxes equal to the amount of qualifying sick and child care leave that they paid, rather than deposit them with the IRS.

The payroll taxes that are available for retention include withheld federal income taxes, the employee share of Social Security and Medicare taxes, and the employer share of Social Security and Medicare taxes with respect to all employees.

If there are not sufficient payroll taxes to cover the cost of qualified sick and childcare leave paid, employers will be able to file a request for an accelerated payment from the IRS. The IRS expects to process these requests in two weeks or less. The details of this new, expedited

procedure will be announced by the Treasury Department.

[See Treasury Department Guidance](#)

Small Business Assistance – Paycheck Protection Program

H.R.748 provides nearly \$350 billion would be provided to small businesses as forgivable loans to bridge the economic shutdown caused by the coronavirus. **A small business DOES NOT have to be closed or experiencing losses to qualify for this important funding.**

Under the bill (HR 748), the Small Business Administration would provide the loans through its existing 7(a) program **in amounts equal to two and a half months of payroll**, with a maximum of \$10 million. As long as the borrower uses the loan to cover payroll, interest on debt, rent or utilities, **the loans would be forgiven.**

The bill would waive most of the SBA's usual paperwork requirements and other prerequisites to speed the money into entrepreneurs' hands. Some paperwork would come on the back end, when companies would need to prove they actually utilized the loans for the intended purpose under the Act.

Interest on the loans would be capped at 4 percent and only the principal of the loans would be forgivable. If a business terminates workers or reduces their pay, the amount forgivable would be reduced proportionately.

Forgiven debt is usually treated as income for tax purposes, but that would not apply to loans under this program, thereby keeping participating companies from being saddled with a larger tax bill next year.

Eligibility for this SBA loan program is capped at not more than 500 employees. The definition of "employee" is defined as individuals employed on a full-time, part-time, or other basis.

<https://www.sba.gov/>

Business, Industry & Local Government Support

The bill provides \$500 billion to the Treasury Department's Exchange Stabilization Fund (ESF) for support loans made by the Federal Reserve and direct loans from the Treasury — including \$454 billion to support loans made by the Fed. Loans or loan guarantees could not be made after Dec. 31, 2020.

In recent weeks, the Treasury has already begun using the ESF to guarantee new lending programs by the Federal Reserve aimed at supporting the economy as the COVID-19 pandemic has worsened, including direct loans issued by the Fed to banks and large employers. In the past two weeks the Fed has established six credit facilities (lending programs that inject liquidity into capital markets) and has plans to open more in an effort to keep U.S. banks and businesses solvent while much of the economy shuts down to slow the pandemic's spread. The Fed has also slashed interest rates to almost zero and is buying unlimited amounts of U.S. Treasuries and mortgage-backed securities from banks in order to keep credit markets functioning smoothly.

The bill directs Treasury to use \$454 billion from the ESF to guarantee and support Federal Reserve programs that provide loans to eligible businesses and state and local governments. Lawmakers estimate the Fed would be able to leverage the \$454 billion to provide anywhere

between \$2 trillion and \$4 trillion in capital into the economy. Loans under the program could not be forgiven.

Stock Buyback & Compensation Restrictions

Under the bill, recipients of Federal Reserve loans supported by the measure would be prohibited from engaging in stock buybacks or paying dividends for one year, or until the loan is paid back. However, the Treasury Department could waive these requirements if it determines it necessary "to protect the interests of the Federal Government."

Borrowers who receive such loans would also be prohibited from increasing the total compensation of any employee whose total compensation exceeds \$425,000 until one year after the loan is repaid. These businesses would also be prohibited from offering any employee a severance package that is more than twice their total annual compensation (a so-called "Golden Parachute").

The measure also limits pay raises for executives who earned more than \$3 million in 2019.

Mid-Sized Businesses

The bill encourages the Treasury Department to work with the Federal Reserve to establish lending programs to support businesses and non-profit groups with between 500 and 10,000 employees that would be ineligible to apply for SBA assistance. If the Fed creates such a program, the loans issued through this facility would be limited to an annual interest rate of 2%, and borrowers would be able to defer repayments for up to six months.

To receive a loan under this program, a borrower must certify that it will: use the funds to retain at least 90% of its workforce at full compensation and benefits through Sept. 30; will not buy back stock or pay dividends while the loan is outstanding; will not outsource jobs until two years after the loan's repayment; and will not try to block union organizing while the loan is outstanding.

Deferral of Payroll Tax Payments

As an additional incentive to keep workers on staff, the Act would allow companies to defer the 6.2 percent Social Security tax on all wages up to \$137,700 for the rest of the year, though an employer would have to pay it back in equal installments in 2021 and 2022. What they owe, though, could be reduced by the tax credits earned by keeping employees on their payroll.

Employee Retention Tax Credit

The bill establishes an employee retention credit for those businesses subject to closure due to COVID-19. It provides a refundable payroll tax credit for 50 percent of wages paid by employers to employees during the COVID-19 crisis. The credit is available to employers whose (1) operations were fully or partially suspended, due to a COVID-19-related shutdown order, or (2) gross receipts declined by more than 50 percent when compared to the same quarter in the prior year.

The credit is based on qualified wages paid to the employee. For employers with greater than 100 full-time employees, qualified wages are wages paid to employees when they are not providing services due to the COVID-19-related circumstances. For eligible employers with 100 or fewer full-time employees, all employee wages qualify for the credit, whether the employer is open for business or subject to a shut-down order. The credit is provided for the first \$10,000 of

compensation, including health benefits, paid to an eligible employee. The credit is provided for wages paid or incurred from March 13, 2020 through December 31, 2020.

Direct Payments to Individuals and Households

The centerpiece of the tax provisions is the inclusion of direct payments to households: \$1,200 for individuals and \$2,400 for joint filers, with an extra \$500 per child. Those amounts phase out by 5 percent of adjusted gross income above \$75,000 for single filers and \$150,000 for married couples. A family of four earning \$200,000 would see their credit reduced to \$900 from the maximum \$3,400.

Retirement Savings Withdrawals and Loans

As with other disasters, Congress will allow no-penalty hardship withdrawals from 401(k)s and other retirement plans as Americans struggle to find cash to make it through the coronavirus pandemic. The legislation contains relaxed rules for taking out loans against retirement savings, for deducting charitable contributions and for taking required minimum distributions from retirement plans.

The bill not only waives the 10 percent early withdrawal penalty from a retirement plan but gives those who make withdrawals three years to return the money to their plan.

*****ACRP will continue to update this document as federal agencies provide guidance on implementation efforts *****