



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

**Economic support and stimulus bill**



**T**he Coronavirus Aid, Relief, and Economic Security (CARES) Act ("CARES Act"), a \$2.2 trillion economic support and stimulus bill, which was passed unanimously by the United States Senate on March 25th will likely be passed by the House and enacted by the President as early as later today.

The CARES Act is the largest economic rescue package in US history. The CARES Act includes \$260 billion to expand and extend unemployment benefits; \$290 billion in one-time checks to eligible Americans; \$377 billion in loans and grants to small businesses; \$510 billion to support loans and loan guarantees for large businesses and government; \$150 billion to support state and local governments; and roughly \$180 billion in health-related spending.

Importantly, the CARES ACT also provides \$130 billion to support healthcare providers as they prepare for, and respond to, the pandemic, including \$100 billion to healthcare providers for COVID-19 related expenses and lost revenue. In addition, the bill relaxes certain telehealth restrictions; lifts the 2% Medicare sequestration through the end of the year; provides hospitals treating COVID-19 patients with a 20% payment increase; extends funding for a number of Medicare and Medicaid programs until December 1, 2020; and delays Medicaid disproportionate share hospital (DSH) reductions until December 1, 2020.

In this brief, we summarize: (1) major provisions of Division A, Title III of the CARES Act on policy changes to support the US healthcare system in its fight against the pandemic and, (2) healthcare-related appropriations included in Division B of the CARES Act. We also provide some high-level implications for consideration by providers on the front lines.

## Supporting America's health care system in the fight against the coronavirus

Division A, Title III of the CARES Act includes important policy changes and appropriations to address supply shortages; access to health care for COVID-19 patients; innovation; the health care workforce and telehealth; payment rate adjustments and care access; health and human services extenders; and over-the-counter drugs. Key provisions of Title III are summarized below.

### Addressing supply shortages

- Requires the **strategic national stockpile** to include personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests (Section 3102) and includes an approved respiratory protective device as a covered medical countermeasure. (Section 3103)
- Requires FDA to **prioritize and expedite reviews** of drug applications and any inspections necessary to mitigate or prevent drug shortages. (Section 3111)
- -Requires **drug manufacturers to report on interruption or permanent discontinuance** in the manufacture of an active pharmaceutical ingredient (API) that is likely to lead to a meaningful disruption supply of a drug necessary to protect the public health or a drug that is life-sustaining (Section 3112) and requires **medical device manufacturers to notify the HHS Secretary of any permanent or temporary interruption** in manufacture of devices critical to public health; creates an expedited pathway for device consideration and facility inspection to mitigate such a shortage; and establishes a public list of devices that are or may be in shortage. (Section 3121)

## Access to health care for COVID-19 patients

- Sets the **price that a commercial insurer will pay for a COVID-19 diagnostic test** as 1) an existing negotiated rate if the insurer and manufacturer have one in effect, or 2) the cash price for the test as published on a website. Manufacturers must publish the cash price or incur a Civil Monetary Penalty of \$300/day. (Section 3202)
- Requires commercial insurers to **cover without cost-sharing “qualifying coronavirus preventive services” (A or B rating from the USPSTF) and vaccines** listed by the CDC within 15 days of the rating or listing. (Section 3203)
- Authorizes and appropriates **\$1.32 billion for community health centers** for the detection, prevention, diagnosis, and treatment of COVID-19 disease. (Section 3211)
- Expands **grant funding for evidence-based telehealth networks** and telehealth technologies by \$29 million for each fiscal year from 2021 through 2025. (Section 3212)
- Expands **rural health care services by \$79.5 million** for each fiscal year from 2021 through 2025. (Section 3213)
- Updates the **authorization and response authority of the U.S. Public Health Service Commissioned Corps and Ready Reserve**. (Section 3214)
- Preempts State law to **provide immunity to any volunteer health professional** for harm caused by simple negligence in providing in good faith treatment in response to and during the COVID-19 public health emergency. (Section 3215)
- Allows HHS Secretary to **reassign members of the National Health Service Corps** to provide health services during the public health emergency. (Section 3216)
- Allows **patients to give a broad authorization to share their health records** (including substance use disorder information), under continued governance of HIPAA. Patients can revoke their authorization; restrictions on law enforcement use are retained. (Section 3221)
- Waives **certain nutrition requirements** under Older Americans Act meal programs to ensure seniors can receive meals. (Section 3222)
- Directs HHS to issue **guidance on the sharing of protected health insurance** information during the COVID-19 emergency period. (Section 3224)

- Appropriates \$125.5 million in funding for each fiscal year from 2021 through 2025 for the **Healthy Start program** to help reduce infant mortality and address health disparities. (Section 3225)
- Directs the HHS Secretary to carry out a **national campaign to improve awareness** of, and support outreach to the public and health care providers about, the importance and safety of **blood donation** and the need for donations for the blood supply during the public health emergency. (Section 3226)

## Innovation

Accelerates **consideration of new animal drugs** if that drug alone or, in combination with another drug, has the potential to treat an animal disease that could cause serious illness in humans. (Section 3302)

## Health care workforce and telehealth

- Requires the HHS Secretary to develop within 1 year a comprehensive and coordinated plan and report concerning the **health care workforce development programs** of HHS, including education and training programs. (Section 3402)
- Authorize grants for the establishment or operation of **Geriatrics Workforce Enhancement Programs**. (Section 3403)
- Creates new **nursing workforce demonstrations**, allows nursing retention grants, and creates clinical nurse specialist programs. (Section 3404)
- Permits **telehealth and other remote care services** to be paid with no deductible without jeopardizing High Deductible Health Plan status under the IRS code for plans that begin on or before December 31, 2021. (Section 3701)
- Permits HSAs after December 31, 2021 to cover menstrual care products as **qualified medical expenses**. (Section 3702)
- Eliminates **limitation of expanded Medicare telehealth services** (under Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020) to situations in which the provider has treated the patient within the last three years. (Section 3703)
- Permits **telehealth services by FQHCs or rural health clinics** during the emergency period at national average physician fee schedule rates and excludes such costs from PPS payment calculations. (Section 3704)

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## Supporting America's health care system (continued)

- Permits the Secretary to **waive the face-to-face periodic evaluations of home dialysis** patients by nephrologists during the emergency period. (Section 3705)
- Permits the Secretary to determine appropriateness of **hospice physicians or nurse practitioners conducting face-to-face encounters** to recertify eligibility via telehealth during the emergency period. (Section 3706)
- Directs the Secretary to consider ways to **encourage use of telecommunications system for remote monitoring** of home health patients, including by guidance and outreach during the emergency period. (Section 3707)
- Directs the Secretary to prescribe regulation effective no later than 6 months after enactment permitting physician assistants, nurse practitioners, and clinical nurse specialists to **order home health services** following a face-to-face encounter, including covered osteoporosis drugs. (Section 3708)

### Important Medicare and Medicaid payment rate adjustments and care access

- Lifts **2% sequestration of the Medicare program** through December 31, 2019. (Section 3709)
- Provides **hospitals** treating Medicare patients for COVID-19 (based on identified DRGs) a **20% payment increase** for all services provided. (Section 3710)
- Waives the **inpatient rehabilitation facility (IRF) "3-hour" rule** (requiring patients receive at least 3 hours of therapy per day for 5 days) and the **long-term care hospital (LTCH) "50-percent" rule** (for facilities that do not have a discharge percentage of at least 50%) and **site-neutral payment rate** for the public health emergency. (Section 3711)
- Prevents a scheduled decrease in payment **amounts for durable medical equipment (DME)** through the length of public health emergency, in order to help patients transition from hospital to home and remain in their home. (Section 3712)
- Ensures permanent **coverage of testing and a coronavirus vaccine** (once one is licensed) under Medicare Part B without cost-sharing. (Section 3713)
- Requires Medicare Prescription Drug Plans and MA-PD plans to **allow fills and refills of covered drugs for up to 90 days** during the public health emergency. (Section 3714)
- Allows state Medicaid programs to **pay for home and community-based services for disabled individuals** in acute care hospitals in order to reduce the length of stay. (Section 3715)

### Health and Human Services extenders

The law extends funding for several healthcare-related programs, initiatives, and policies:

- Medicare: Extends the **work geographic index floor** under Medicare through December 1, 2020 (Section 3801); funding for **quality measure endorsement, input, and selection** increased to \$20 million for FY2020 and a pro-rated amount October 1 to November 30, 2020 (Section 3802); and funding outreach and assistance for **low-income programs** at \$13 million for FY2020 and a pro-rated amount October 1 to November 30, 2020. (Section 3803)
- Medicaid: Delays **Medicaid disproportionate share hospital (DSH)** reductions until December 1, 2020 (Section 3813); Extends funding for **Money Follows the Person** rebalancing demonstration program at \$337.5 million for or FY2020 and a pro-rated amount through November 30, 2020 (Section 3811); and extends and expands the **Community Mental Health Services demonstration** program through November 30, 2020. (Section 3814)
- Other Health Programs: Extends funding for the **Temporary Assistance for Needy Families (TANF)** program through November 30, 2020 (Section 3824); **community health centers** at \$4 billion for FY2020 and a pro-rated amount October 1 to November 30, 2020; the **National Health Service Corps** at \$310 million for FY2020 and a prorated amount from October 1 to November 30, 2020 (Section 3831); and, **diabetes programs** at \$96.6 million for FY2020 and \$25 million from October 1 to November 30, 2020. (Section 3832)

### Over-the-counter (OTC) drugs

Integrates the **Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019**, which establishes an **FDA user fee program for OTC drugs**, reforms the OTC drug review process, provides innovative OTC drugs 18 months of exclusivity, and provides FDA authority to respond to OTC drug safety issues. It also amends certain provisions in the Sunscreen Innovation Act, allowing a sponsor to request confidential meetings regarding a proposed sunscreen order and to discuss anything involving confidential commercial information or trade secret

## Emergency appropriations for coronavirus health response and agency operations

Division B of the CARES Act includes important appropriations available to healthcare related agencies, providers, and entities preparing for and/or responding to the COVID-19 emergency, including the following:

### Department of Health and Human Services (\$140.4 billion)

- **Reimbursement to Hospitals & Healthcare Providers:** \$100 billion to ensure healthcare providers continue to receive the support they need for COVID-19 related expenses and lost revenue.
- **Strategic National Stockpile:** \$16 billion to procure personal protective equipment, ventilators, and other medical supplies for federal and state response efforts. Combined with the first supplemental appropriations, approximately \$17 billion has been provided for the Stockpile.
- **Vaccine, Therapeutics, Diagnostics, and other Medical or Preparedness Needs:** \$11 billion, including at least \$3.5 billion to Biomedical Advanced Research and Development Authority (BARDA) to advance construction, manufacturing, and purchase of vaccines and therapeutic delivery to the American people.
- **Hospital Preparedness:** \$250 million to improve the capacity of healthcare facilities to respond to medical events
- **Health Resources and Services Administration (HRSA):** \$275 million to expand services and capacity for rural hospitals, telehealth, poison control centers, and the Ryan White HIV/AIDS program. Community Health Centers may use FY2020 funding to maintain or increase staffing and capacity to address the coronavirus.
- **HHS Office of the Inspector General (OIG):** \$4 million for oversight activities.
- **CDC, State and Local Preparedness Grants:** \$1.5 billion for state and local preparedness and response activities. Combined with the first supplemental appropriations, \$2.5 billion has been provided for state and local needs.
- **CDC, Global Health Security:** \$500 million to continue CDC's global health efforts that are critical to the health and security of the United States. Combined with the first supplemental appropriations, \$800 million has been provided for global health.

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# \$100,000,000,000 for Eligible Health Care Providers

Included in a "Public Health and Social Services Emergency Fund" is \$100,000,000,000 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.

To be eligible for a payment under this paragraph, an eligible health care provider shall submit to the Secretary of Health and Human Services an application that includes a statement justifying the need of the provider for the payment and the eligible health care provider shall have a valid tax identification number. "[E]ligible health care providers" means public entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit entities and not-for-profit entities not otherwise described in this proviso as the Secretary may specify, within the United States (including territories), that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID-19. The Secretary of Health and Human Services shall, on a rolling basis, review applications and make payments under this paragraph. The term "payment" means a pre-payment, prospective payment, or retrospective payment, as determined appropriate by the Secretary. Payments under this paragraph shall be made in consideration of the most efficient payment systems practicable to provide emergency payment.

These funds may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse. Funds appropriated under this paragraph shall 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. Recipients of payments shall submit reports and maintain documentation as the Secretary determines are needed to ensure compliance with conditions that are imposed by this paragraph for such payments, and such reports and documentation shall be in such form, with such content, and in such time as the Secretary may prescribe for such purpose.



## Supporting America's health care system (continued)

- **CDC, Public Health Data Surveillance and Infrastructure Modernization:** \$500 million to invest in better COVID-19 tools and build state and local public health data infrastructure.
- **CDC, Infectious Disease Fund:** \$300 million to give HHS flexibility to respond to pandemic threats. Combined with the first supplemental appropriations, \$600 million has been provided to this fund.
- **National Institutes of Health (NIH):** \$945.5 million for vaccine, therapeutic, and diagnostic research to increase our understanding of COVID-19, including underlying risks to cardiovascular and pulmonary conditions. Combined with the first supplemental appropriations, \$1.78 billion has been provided for NIH research.
- **SAMHSA, Certified Community Behavioral Health Clinics:** \$250 million to increase access to mental health care services.
- **SAMHSA, Suicide Prevention:** \$50 million to provide increased support for those most in need of intervention.
- **SAMHSA, Emergency Response Grants:** \$100 million to address mental health, substance use disorders, and provide resources and support to youth and the homeless during the pandemic.
- **Centers for Medicare and Medicaid Services:** \$200 million, including \$100 million to support additional infection control surveys for facilities with populations vulnerable to severe illness from coronavirus.
- **Administration for Family Living:** \$955 million, including resources for aging and disability services programs, such as senior nutrition; home and community-based supportive services; family caregivers; elder justice; and independent living.

### Department of Agriculture

**Food and Drug Administration (FDA):** \$80 million to continue efforts related to shortages of critical medicines, enforcement work on counterfeit and misbranded products, emergency use authorizations and pre- and post-market work on medical countermeasures, therapies, vaccines, and research.

### Department of Defense

- **Defense Production Act:** \$1 billion to invest in manufacturing capabilities that are key to increasing the production rate of personal protective equipment and medical equipment to meet the demand of healthcare workers all across the nation.
- **Medical Care and Medical Countermeasures:** \$1.8 billion to address increased healthcare cases for eligible military members, dependents, and retirees; and to procure additional medical equipment; as well as for the procurement of physical protective equipment for medical personnel and disease response.
- **Military Healthcare System Direct Care Capacity:** \$1.6 billion for the expansion of military treatment facilities to ensure maximum capacity of the direct care system, and to procure expeditionary hospital packages.
- **Research and Development:** \$415 million for the development of vaccines, antivirals, 24/7 lab operations and the procurement of diagnostic tests.
- **Non-medical Protective Equipment and Other Supplies:** \$627.5 million for procurement of pharmaceuticals and physical protection equipment by the military Services for installations, ships, first responders; and for biohazard mitigation.
- **Defense Health Program Private Sector Care:** \$1.1 billion for additional shortfalls in defense private sector care.

### Department of Homeland Security

**Federal Emergency Management Administration (FEMA):** \$45.4 billion to continue FEMA's entire suite of response and recovery activities and reimbursements provided to states and localities nationwide by the Disaster Relief Fund for emergency and major disaster declarations, as well as funding for FEMA facilities and information technology required to support FEMA's lead role in coordinating federal response activities. The bill also includes \$400 million for grants that can be disbursed in a timely manner for firefighters, emergency managers, and providers of emergency food and shelter to ensure healthcare providers continue to receive the support they need for COVID-19 related expenses and lost revenue.

## Department of Veterans Affairs

- **Medical Services:** \$14.4 billion to support increased demand for healthcare services at VA facilities and through telehealth, including the purchase of medical equipment and supplies, testing kits, and personal protective equipment. Also enables VA to provide additional support for vulnerable veterans, including through programs to assist homeless or at-risk of becoming homeless veterans, as well as within VA-run nursing homes and community living centers.
- **Medical Community Care:** \$2.1 billion to support increased demand for care in the community, specifically emergency room and urgent care.
- **Medical Emergency Management:** \$100 million to support the Veterans Health Administration's 24-hour emergency management coordination, including overtime, travel, transportation of materials, and training.
- **Medical Facilities:** \$606 million to support development of alternative sites of care and procurement of mobile treatment centers to meet the demand for healthcare services, improvements in security, and non-recurring maintenance projects to existing infrastructure and utility systems at VA facilities (e.g., reconfiguration of space to support care).
- **Information Technology:** \$2.15 billion to support increased telework, telehealth, and call center capabilities to deliver healthcare services directly related to coronavirus and mitigate the risk of virus transmission.
- **Grants for Construction of State Extended Care Facilities:** \$150 million to support modification or alteration of existing hospital, nursing home, and domiciliary facilities in state homes to prevent, prepare for, and respond to coronavirus.

## Implications for Providers

As noted previously, the legislation is the largest economic stimulus bill in US history, and includes a large infusion of funding into the healthcare sector. In addition to the massive \$100 billion appropriation to hospitals and eligible providers for "COVID-19 related expenses and lost revenue," the legislation also appropriates \$275 million for rural hospitals, telehealth, poison control centers and HIV/AIDS programs; \$250 million for hospital capacity expansion and response; and \$150 million for modifications of existing hospital, nursing home and "domiciliary facilities" in response to the coronavirus.

In addition to supplemental funding to support hospitals and other providers for the duration of the public health emergency, the legislation also provides some payment policy relief for providers. These provisions include suspending the 2% Medicare sequester through Dec. 31, 2020; increasing by 20% any Medicare payment to hospitals for the treatment of a patient admitted with COVID-19; and delaying the \$4 billion in scheduled cuts to Medicaid Disproportionate Share Hospital (DSH) payments through November 30, 2020. In addition, relaxed regulatory requirements for some facilities include a waiver of the IRF "three-hour rule" and the LTCH "50-percent rule;" a temporary pause of LTCH site-neutral payments; relaxation of telehealth service requirements; and permitting additional clinician types to order home health services.

Enactment of this legislation will be the first step in the process to authorize the Administration to distribute the CARES Act funds. We expect a coming tsunami of additional guidance and regulatory process to be put in place to assure appropriate use of the CARES Act appropriations in response to this global emergency. Providers should also expect government oversight of CARES Act spending. We will be reporting on these regulatory processes for application for, and distribution of, CARES Act funds as further information becomes available.

**As always, if you or your clients have any questions about these COVID-19 developments or other federal healthcare initiatives, please contact Larry Kocot, Tracey McCutcheon, or Ross White.**

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