

The Coronavirus Aid, Relief, & Economic Security (CARES) Act

Summary of the COVID-19 Stimulus Package

The Coronavirus Aid, Relief and Economic Security Act (CARES Act), provides for \$2 trillion for “emergency assistance and health care response for individuals, families and businesses affected by the 2020 coronavirus pandemic” and was signed into law on March 27, 2020. Summarized below are the major business and healthcare related elements impacting the regenerative medicine sector. This overview also includes relevant provisions included in the \$8.3 billion supplemental appropriations bill signed into law on March 6, 2020.

BUSINESS/EMPLOYER/EMPLOYEE PROVISIONS

Emergency Small Business Relief Provisions

The CARES Act expands both lender and borrower eligibility for 7(a) loans and provides more protections for lenders. It also authorizes \$349 billion for the expanded Section 7(a) loan program

- *Eligibility:* Expands eligibility to include (1) businesses under 500 employees; (2) the size standards established by SBA for the industry in which the business operates; and (3) multiunit accommodation and food service businesses with less than 500 employees at a particular location even if the business has, in aggregate, more than 500 total employees.
- *Loan Forgiveness:* Converts loans into grants if the loan is used to cover mortgage interest, rent payments, utility payments or payroll costs, which includes salary (up to \$100K), health insurance premiums, sick leave, cash tip payment, retirement benefits and state and local employment taxes. Forgiveness is reduced if the employer reduces his average full time equivalent (FTE) employees.
- *SBA Disaster Loans and Grants:* Provides \$10 billion for the SBA to provide Economic Injury Disaster Loans until December 31, 2020. It also authorizes SBA to give grants (up to \$10,000) to entities eligible for a loan within 3 days of receiving an application to cover immediate covered expenses.
- *SBA Express Loans:* Increases the maximum SBA Express loan from \$350,000 to \$1 million through Dec. 31, 2020.
- *Current SBA Loan Forbearance:* Provides \$17 billion to cover 6 months of payments of loan payments on existing SBA 7(a) loans, Certified Development Company loans, and microloans.

- *Distressed Business Loans*: Provides an additional \$425 billion for the Coronavirus Economic Stabilization Fund led by the Treasury available to distressed businesses of all sizes with a number of limitations.

Mid-Sized Businesses

Treasury and the Federal Reserve are going to collaborate on a special Federal Reserve program for mid-sized businesses (between 500 – 10,000 employees) that will have special terms relating to 90 percent employee retention, with full compensation and benefits through Sept 30, a prohibition on offshoring jobs for the term of the loan plus 24 months, maintain existing union agreements for the term of the loan plus 24 months and "remain neutral" on any attempts of employees to unionize for the term of the loan.

Unemployment Insurance

CARES creates a temporary Pandemic Unemployment Assistance program beginning January 27, 2020 through December 31, 2020, to provide payment to those not traditionally eligible for unemployment benefits (self-employed, independent contractors, those seeking part-time employment, those with limited work history, and others) who are unable to work as a direct result of the coronavirus public health emergency.

- A covered individual is one who is not eligible for regular compensation or extended benefits under state or federal law, and self-certifies that he or she is otherwise able to work but is unable to do so for reasons related to the impacts of COVID-19 on the individual, the individual's family, the individual's place of work, movement restrictions and more.
- Provides payment to states to reimburse nonprofits, government agencies and Indian tribes for half of the costs they incur through December 31, 2020 to pay unemployment benefits.
- Provides an additional \$600 per week payment to each recipient of unemployment insurance or Pandemic Unemployment Assistance for up to four months.
- Provides funding to pay the cost of the first week of unemployment benefits through December 31, 2020 for states that choose to pay recipients as soon as they become unemployed instead of waiting one week before the individual is eligible to receive unemployment benefits.
- For the Pandemic Unemployment Assistance, assistance is available for up to 39 weeks and the total shall include any week for which the covered individual received regular compensation or extended benefits under any federal or state law. If after the date of enactment of the act the duration of extended benefits is extended, the 39-week period will be extended by the number of weeks that is equal to the number of weeks by which the extended benefits were extended.
- Provides funding to support "short-time compensation" programs where employers reduce employees' hours instead of laying them off and the employees with reduced hours receive a pro-rated unemployment benefit. This provision would pay 100 percent of the costs they incur in providing short-time compensation through December 31, 2020.

- Gives the secretary of the Department of Labor the authority to issue operating instructions or other guidance as necessary in order to implement this subtitle, as well as allowing the Labor Department to waive Paperwork Reduction Act requirements, speeding up their ability to gather necessary information from the states.

Employee Retention/Business Taxes

Provides an employee retention credit for eligible employers. Credit is 50 percent of qualified wages (limited to \$10,000 per employee, per quarter) and is further limited by employment taxes but is thereafter refundable. Qualified wages include health plan expenses.

- Provides for deferral of payment of the 6.2 percent payroll tax paid by both employers and self-employed individuals for the Social Security Trust Fund.
- Relaxes the rules on the limitations on the use of net operating losses. Businesses can carry back losses for five years and removes the taxable income limitation for carry forwards.
- Accelerates the ability for corporations to use alternative minimum tax credits and allowing businesses to claim a credit as a result.
- Temporarily increases the amount of interest expenses businesses are allowed to deduct, from the current 30 percent limitation to 50 percent.
- Enables businesses to immediately write off the costs of qualified improvement property.
- Temporarily suspends excise tax for alcohol used to produce hand sanitizer.

501(c)(3) Organizations

501(c)(3) non-profit organizations are eligible for the Emergency Small Business Administration 7(a) loans and employee retention tax credit outlined above.

Paid Family and Medical Leave/Sick Leave

CARES establishes a limitation on Paid Family and Medical Leave under the Families First Act, stating an employer shall not be required to pay more than \$200 per day and \$10,000 in the aggregate for each employee under this section. Creates a limitation stating an employer shall not be required to pay more than \$511 per day and \$5,110 in the aggregate for sick leave or more than \$200 per day and \$2,000 in the aggregate to care for a quarantined individual or child for each employee under this section.

- Allows an employee who was laid off by an employer March 1, 2020, or later to have access to paid family and medical leave in certain instances if they are rehired by the employer.
- Employee would have had to work for the employer at least 30 days prior to being laid off.

- Allows employers to receive an advance tax credit from Treasury instead of having to be reimbursed on the back end.
- Provides single employer pension plan companies with more time to meet their funding obligations by delaying the due date for any contribution otherwise due during 2020 until January 1, 2021. At that time, contributions due earlier would be due with interest.

HEALTHCARE PROVISIONS

National Institutes of Health (NIH)

\$945 million is allocated to support the expansion of research plans under the first supplemental, including developing an improved understanding of the prevalence of COVID-19, its transmission and the natural history of infection, and novel approaches to diagnosing the disease and past infection, and developing countermeasures for prevention and treatment.

Centers for Disease Control and Prevention (CDC)

\$4.3 billion is provided to support federal, state, and local public health agencies to prevent, prepare for, and respond to the coronavirus. Included in the appropriation is \$1.5 billion in flexible funding to support CDC's continuing efforts to contain and combat the virus, including repatriation and quarantine efforts, purchase and distribution of diagnostic test kits (including for state and local public health agencies) and support for laboratory testing, workforce training programs, combating antimicrobial resistance and antibiotic resistant bacteria as a result of secondary infections related to COVID-19, and communicating with and informing public, state, local, and tribal governments and healthcare institutions.

Biomedical Advanced Research and Development Agency (BARDA)

- \$3.5 billion is appropriated for the BARDA to support the development of countermeasures, vaccines, and other technologies, treatments, and therapies.
- \$27 billion earmarked for BARDA to support a wide range of preparedness and response activities, to remain available through FY 2023, for a domestic and international response, including (i) the development of countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies; (ii) medical surge capacity; (iii) addressing blood supply chain, workforce modernization, telehealth access and infrastructure, novel dispensing, enhancements to the U.S. Commissioned Corps, and (iv) other preparedness and response activities. Up to \$16 billion of this amount may be used to procure items for the Strategic National Stockpile.
- Removes limitations and grant cap (\$100 million) on other arrangements (beyond contracts, grants, cooperative agreements, etc.) between the BARDA and external entities in the development of medical countermeasures during a public health emergency.

Hospitals and Health Care Providers

\$100 billion is provided, through grants or other mechanisms, to "eligible health care providers" to cover unreimbursed healthcare-related expenses or lost revenues attributable to the public health emergency resulting from the coronavirus. The funds are subject to several stipulations, including but not limited to:

- Eligible entities are public entities, Medicare or Medicaid enrolled suppliers and providers, and such for-profit and nonprofit entities as the Secretary may specify that provide diagnosis, testing, or care to individuals that have or may have COVID-19.
- Funds can be used for the construction of temporary structures, leasing of properties, medical supplies and equipment including personal protective equipment and testing supplies, increased workforce and training, emergency operation centers, retrofitting facilities, and surge capacity. □ Pre-payment, prospective payment, or retrospective payment, as determined appropriate by the Secretary, are all allowed.

National Institute of Standards and Technology (NIST)

The bill includes \$6 million for the National Institute of Standards and Technology to provide continuity of operations and to conduct research and measurement science to support testing and treatment of coronavirus and \$75 million for the National Science Foundation (NSF) to support research at molecular, cellular, physiological and ecological levels to better understand coronavirus genetics, modes of action, transmission, virulence and population dynamics.

Department of Defense

\$415 million for is appropriated for military medical research and development for promising vaccines and anti-viral pharmaceuticals.

Addressing Supply Shortages

National Academies Report: Requires DHHS to contract with the National Academies of Science to perform a study and report on the medical product supply chain within 60 days. The report will assess and evaluate the dependence of the private sector, state, and federal government on critical drugs and devices that are sourced or manufactured outside the U.S.

Strategic National Stockpile to Include Certain Medical Supplies: Requires the Strategic National Stockpile to include personal protective equipment, ancillary medical supplies, and other applicable supplies as are necessary for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests.

Prioritize Review of Certain Drug Applications: Requires the FDA to prioritize and expedite reviews of drug applications and any inspections necessary to mitigate or prevent drug shortages.

Additional Reporting Requirements: Expands drug manufacturer reporting requirements to include active pharmaceutical ingredients in the event of an interruption or permanent discontinuance in the manufacture of an active pharmaceutical ingredient if that is likely to lead to a meaningful disruption in the supply of the ingredient of a drug needed to protect the public health during a public health emergency, or a drug that is life sustaining, life-

supporting, or intended for use in the prevention or treatment of a debilitating disease or condition. It also requires manufacturers to develop risk management plans.

Medical Device Shortages

Discontinuance or Interruption of Production of Medical Devices: Requires manufacturers of medical devices that are critical to the public health during a public health emergency are life-supporting or life-sustaining to report certain discontinuances or interruption of the manufacture of the device it is likely to disrupt the supply of the device.

Preventing Medical Device Shortage: Requires manufacturers of devices critical to the public health (i.e., those life-supporting or sustaining) to notify the Secretary of HHS of any permanent or temporary interruption in manufacture of the device, and; creates an expedited pathway for device consideration and facility inspection of a facility to mitigate such a shortage; establishes a public list of devices that are or may be in shortage.

COVID-19 Vaccine Coverage

Coverage of the COVID-19 Vaccine under Part B: Ensures that access to testing and a coronavirus vaccine (once one is licensed) would be quickly covered without cost-sharing permanently.

Requiring Medicare Prescription Drug (P.D.) Plans and M.A.–P.D. plans to Allow During the COVID-19 Emergency Period for Fills and Refills of Covered Part D Drugs for up to a 3-month supply - The plans as mentioned above must permit a part D eligible individual enrolled in such a plan to obtain in a single fill or refill, the total day supply (not to exceed a 90-day supply). This is effective January 27, 2020, through the end of the COVID-19 emergency as declared by the HHS Secretary under the PHS Act Section 319.

COVID-19 Testing Products Coverage

Clarification Regarding Coverage of COVID-19 Testing Products: expands Medicaid coverage without cost-sharing to experimental COVID in-vitro diagnostic products that have not been approved through certain approval processes under the Food, Drug, and Cosmetic Act (Sections 510(k), 513, 515, or 564).