

# Government Relations

## Legal Alert

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## A New Marshall Plan: Congress Nears Passage of CARES Act

After midnight on the East Coast on Wednesday, March 25, negotiators from the U.S. Congress and Trump Administration finally agreed to the framework of a historic \$2 trillion bill. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) constitutes a new Marshall Plan for our nation. Congress is expected to approve this landmark legislation swiftly, which will set off an unprecedented flurry of activity at federal agencies as they implement wide-ranging provisions that will quickly send critically needed funding to all sectors of the U.S. economy and to individuals.

### [Download the CARES Act Final Legislative Text](#)

Arent Fox professionals in the Government Relations, Finance, Tax, Health Care, Labor & Employment, Real Estate, Food and Drug, and other practice groups have been actively engaged during the development of this legislation. We have reviewed this comprehensive bill and have prepared the following summaries of key provisions for our clients. We look forward to the opportunity to help our clients navigate the legislation, agency implementation, and the application of its diverse initiatives to your enterprises.

Among the most salient provisions are:

- Establishment of a \$500 billion loan guarantee program for larger companies as well as nonprofits from 500 to 10,000 employees that the Treasury Department will implement within 10 days.
- \$350 billion for new small business lending that includes companies, nonprofits, and others with up to 500 employees (and, in some limited exceptions for larger businesses).
- Deferral of the payment by employers of the 6.2 percent payroll tax for their employees until Dec. 31, 2021.
- Additional enhancements to employee sick leave and family and medical leave laws as well as significant new funding for unemployment

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insurance.

- \$100 billion in direct financial assistance to hospitals, \$1.3 billion in supplemental funding for community health centers, and other provisions designed to cover costs of diagnosis and treatment of COVID-19 and the financial losses healthcare providers are facing.
- Provisions aimed at getting vaccines and medications for COVID-19 developed and approved more quickly
- One-time payments for each American (\$1,200) and child (\$500) with phasing out at higher income levels.
- Additional funding for safety net programs such as \$900 million for the Low Income Heating and Energy Assistance Program, which helps low-income families with energy bills; and \$15.5 billion for the Supplemental Nutrition Assistance Program, which provides low-income families with healthy food.

## General Business Provisions

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### Emergency Relief for Industries and Large Employers

In an effort to support industries struggling due to the coronavirus epidemic, the CARES Act sets aside \$500 billion for loans and loan guarantees. The package sets aside:

- \$25 billion for airlines;
- \$4 billion for cargo carriers;
- \$17 billion for businesses essential to maintaining national security; and
- \$454 billion for other businesses

The \$454 billion would be allowed for loans, loan guarantees, and to help the Treasury Department and Federal Reserve provide liquidity to the financial system. Treasury would need to promulgate the implementing guidelines within 10 days of enactment. Loan guarantees wouldn't be any longer than five years. Businesses receiving loans must, until September 30, 2020, maintain at least 90% of their employment levels as of March 24, 2020.

Treasury will endeavor to implement a special facility through the Federal Reserve targeted specifically at nonprofit organizations and businesses with between 500 and 10,000 employees, subject to additional criteria and obligations including: the funds received must be used to retain at least 90% of the recipient's workforce, with full compensation and benefits, through September 30, 2020; the recipient cannot outsource or offshore jobs for two years beyond the loan term, it cannot abrogate existing collective bargaining agreements for two years beyond the loan term and it must remain neutral in any union organizing effort for the term of the loan.

The bill bans loan recipients from share buybacks and halts dividends for

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one year, blocks loan forgiveness for recipients, and allows the government to participate in gains of business through warrants, options, stock, or other financial instruments. Pay above \$425,000 is frozen until one year after the loan is no longer outstanding. No retirement or severance packages can exceed twice the maximum total compensation during 2019. Raises for officers and executives earning over \$3 million in 2019 is limited. To provide support to air carrier and support workers, payments to air carriers and airport contractors are to be made within 10 days of request for financial assistance. The bill also requires air carriers that receive loans to maintain the routes that were in service before March 1, 2020 to the best extent possible. The package suspends certain aviation excise taxes.

### Payroll Tax Deferral

Additionally, the CARES Act allows employers and self-employed individuals to defer payment of the 6.2 percent employer share of Social Security taxes through the end of the 2020. Half of deferred amount of Social Security taxes would be due by the end of 2021, and the other half would be due by the end of 2022.

### Modifications for Net Operating Losses

The package also would allow net operating losses from tax years beginning after Dec. 31, 2017, and before Jan. 1, 2020 to be carried back five years. In addition, the Cares Act would temporarily remove the taxable income limitation (enacted in the Tax Cuts and Jobs Act in 2017) that would otherwise limit the deductibility of net operating losses to 80% of taxable income.

### Increase in Business Interest Deduction Limitation

The CARES Act temporarily increases the limitation on the amount of interest that businesses are permitted to deduct on their tax returns by increasing the 30-percent limitation to 50 percent of taxable income (subject to limitations and adjustments) for 2019 and 2020.

## Small Business Provisions

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### Paycheck Protection Program

The CARES Act includes the Keeping American Workers Paid and Employed Act and its \$349 billion "Paycheck Protection Program" for small businesses.

The Paycheck Protection Program provides short-term cash flow assistance to small businesses to help these business and their employees deal with the immediate economic impact of COVID-19. Loans are made by lenders and guaranteed by the federal government. The Small Business Association will administer the Paycheck Protection Program.

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The Paycheck Protection Program is retroactive to Feb. 15, 2020, to help employers not only maintain current workers on their payroll but also to encourage employers to bring already laid-off workers back onto their payrolls.

Small businesses include small businesses, 501(c)(3) nonprofits, 501(c)(19) veteran's organizations and Tribal business concerns that have not more than 500 employees or not more than the applicable size standard for its industry, as provided by the SBA, if higher. Eligible small businesses also include sole-proprietors, independent contractors, or other self-employed individuals. The Paycheck Protection Program also allows small businesses with more than one location, such as restaurant chains and hotels, to have the 500 person limit apply by location, not overall.

Paycheck Protection Program loans can be as large as 250% of a small business's average monthly payroll, not to exceed \$10 million. Payroll expenses include salaries, wages, cash tips, health care benefits, such as insurance premiums, retirement contributions, and paid leave.

The loan may be used to pay salaries, paid leave, insurance premiums, mortgages, rent, and utility bills. Loans can be repaid over ten (10) years, have a maximum interest rate of four percent. There are provisions for payment deferment. In addition, the first eight weeks of the loan may be forgiven, if used to cover payroll costs, interest payments on mortgages, rent, and utilities and appropriate documentation is provided.

The amount of the loan that may be forgiven cannot exceed the principal amount of the loan, and eligible payroll costs do not include compensation over \$100,000.

To get the full benefit of the loan forgiveness, small businesses must keep their employees and pay them at least 75% percent of their prior-year compensation. To encourage employers to re-hire works laid off by the COVID-19 crisis, employers that re-hire previously laid-off workers will not be penalized for having a reduced payroll at the beginning of the period. The SBA will purchase any loan forgiveness amounts from its certified lenders and this cancelled indebtedness will not result in taxable income to the respective small businesses.

In addition to the Paycheck Protection Program, the Keeping American Workers Paid and Employed Act portion of CARES includes \$265 million to support SBA partners in offering counseling, training, and other COVID-19 related assistance to small businesses, \$10 million to support the Minority Business Development Agency to provide similar services and \$10 billion for SBA Economic Injury Disaster Loans, as well as funds for SBA administrative expenses. EIDLs allow small businesses to get \$10,000 within three days, to maintain payroll and satisfy other debt obligations.

### Supporting Minority-Owned Small Businesses

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The CARES Act also awards \$10 million to the Minority Business Development Agency (MBDA) to provide grants to the agency's Minority Business Centers to provide training, education, and advice to minority-owned small businesses and minority chambers of commerce. The MBDA's efforts would focus on helping minority-owned businesses access and apply for resources relating to access to capital and business resiliency at federal agencies. MBDA would also educate minority-owned businesses about the hazards of coronavirus and prevention efforts, the effects of coronavirus on supply chains, distribution, and product sales, mitigating cyber threats while teleworking, and how to manage employees while teleworking to reduce transmission of coronavirus.

### Supporting Small Business and Nonprofit Contracting

In order to provide contractors with additional flexibility, the CARES act allows federal agencies to reimburse contractors each week at the contract billing rate for 40 hours of work, including sick leave. These payment would be provided to keep employees on payroll and pay subcontractors and would only be allowed for contractors whose employees can't telework or work at approved sites, federally-owned, or leased sites due to coronavirus.

### Employee Retention Credit

The CARES Act also creates a refundable tax credit for businesses and nonprofit organizations that close temporarily (on a full or partial basis) due to government orders and whose revenue shrinks by more than 50% from the same quarter in 2019. The tax credit would be allowed for 50% of compensation, including health benefits (up to \$10,000 per employee) paid for each employee during the closure, which amount would be creditable against payroll taxes, with any excess amount refundable. The employee retention credit would apply only to wages paid after Mar. 12, 2020, and it would be reduced by certain payroll tax credits available under the Families First Coronavirus Response Act. Employers that take covered loans under the Paycheck Protection Program mentioned above are not eligible for the employee retention credit.

### Employment Law/Leave Policies

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Just last week as a part of the second coronavirus relief package, Congress implemented a public health emergency leave program under the Family and Medical Leave Act (FMLA) and a paid sick leave program for employees impacted by the coronavirus. Both leave programs apply to employers with 499 employees or fewer and set payment calculations for employers based upon whether the employees are on staff full-time or hourly. Under both types of leave programs, the Secretary of Labor has the authority to exempt employers with fewer than 50 employees where compliance with the paid leave requirements would jeopardize the viability of the business as a going concern, as well as employers of first responders and medical professionals.

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The Emergency Family & Medical Leave Expansion Act provision requires covered employers to offer leave to eligible employees who are unable to work (or telework) due to a need to care for a child under 18 years of age because the child's school or place of care has been closed. Employees are eligible for leave only if they have been employed for 30 days, and allows the first ten days of leave to be unpaid. The law does allow employees to elect to concurrently use any previously accrued paid vacation, personal, medical, or sick leave during the unpaid period of leave. After the tenth day of unpaid leave, covered employers would be required to provide paid leave for each day an employee takes leave at a rate equal to 66.67% of their normal pay.

Likewise, the Emergency Paid Sick Leave Act passed last week requires covered employers to provide paid sick leave to employees for qualifying reasons, which must be immediately made available to employees regardless of how long the employee has been employed. Full-time employees are entitled to 80 hours of paid sick leave, and part-time employees are entitled to a number of hours equal to the number of hours that the employee works, on average, over a two week period. The law bans employers from requiring employees to use other paid leave before using paid sick time under the emergency paid sick leave program.

The CARES Act seeks to put guardrails around current the paid leave laws passed last week by limiting the amount that employers have to pay for both types of leave. H.R. 748 ensures that:

- Employer costs for paid leave under the Emergency Family & Medical Leave Expansion Act related to coronavirus are limited to \$200 per day and \$10,000 per employee in the aggregate.
- Employer costs under the Emergency Paid Sick Leave Act related to coronavirus are limited to \$511 per day and \$5,110 per employee in the aggregate if:
  - The employee is subject to government quarantine due to coronavirus;
  - The employee is experiencing symptoms of coronavirus and needs an examination or medical diagnosis; or
  - The employee has been advised by a health care provider to self-quarantine due concerns related to coronavirus.
- Employer payments under the Emergency Paid Sick Leave Act related to coronavirus are limited to \$200 per day and \$2,000 per employee if:
  - The employee is caring for someone who is subject to government quarantine due to coronavirus, who is experiencing symptoms of coronavirus, or who needs an examination or medical diagnosis related to coronavirus; or
  - The employee is caring for a child whose school/child care has

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closed due to coronavirus.

Employers wouldn't be required to provide paid leave for an employee after paying for 80 hours of paid sick leave, or after the employee returns from taking either type of paid leave mentioned above.

The CARES Act allows employees who were laid off on Mar. 1, 2020 or later to have access to paid family and medical leave in certain instances if they are later re-hired by the employer, but only if the employee had worked for the employer for at least 30 days prior to being laid off.

Finally, the paid leave legislation enacted last week provide for refundable payroll tax credits to employers to cover 100 percent of the cost of providing paid leave to employees under both the sick leave and family leave programs. The CARES Act authorizes the Treasury Department to provide employers with advance tax credits to cover the costs of paid leave, rather than requiring them to later seek reimbursement.

### Advanced Refundable Employer Tax Credits

The second coronavirus package that Congress enacted last week created payroll tax credits for employers to cover 100 percent of the cost of providing paid sick and family leave to employees. It also made the employer tax credits refundable if they exceed the amount the employer owes in payroll tax and ensured the credits would be in effect for wages through the end of 2020.

The CARES Act builds upon those changes by ensuring that the tax credits for paid sick leave can be taken in advance. This legislation also waives any penalties for employers who fail to pay the payroll tax due to anticipation of receiving a tax credit.

### State Relief Fund

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The Cares Act also includes \$150 billion for state and local governments to offset costs due to the coronavirus. The minimum payment for states in 2020 would be \$1.25 billion and adjusted on a proportional basis among states and local governments based upon population.

### Individual Financial Relief

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#### Pandemic Unemployment Assistance

The CARES Act creates an expanded unemployment program through

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Dec. 31, 2020 for people who aren't eligible for regular benefits under state and federal unemployment programs because they have exhausted their regular unemployment benefits. The package also allows states to boost the amount of weekly unemployment insurance due to coronavirus by \$600 through Jun. 30, 2020, which would be fully reimbursed by the federal government. Recipients of Pandemic Unemployment Assistance would have to certify that they are able to work, but are unemployed, partially unemployed, or can't work because:

1. The individual has been diagnosed with coronavirus or is experiencing symptoms;
2. A member of their household has been diagnosed with coronavirus;
3. The individual is providing care for a family member, or member of their household, who has been diagnosed with coronavirus;
4. A child or other person in the household that the individual cares for is unable to attend school due to coronavirus;
5. The individual is unable to go to work because there is a coronavirus quarantine;
6. The individual is unable to go to work because a health care provider has told them to self-quarantine;
7. The individual was scheduled to begin working and does not have a job; or is unable to reach their job, due to coronavirus;
8. The individual has become the head of household or breadwinner because of coronavirus;
9. The individual has to quit their job due to coronavirus;
10. The individual's job is closed due to coronavirus; or
11. The individual is self-employed and seeking part-time employment, does not have sufficient work history, or wouldn't qualify for regular unemployment and becomes unemployed or can't find work.

The CARES Act's expanded unemployment insurance provisions do not apply for people who are able to telework with pay or to people who are receiving paid leave benefits – including paid sick leave. The expanded unemployment provisions would cover people for coronavirus-related unemployment beginning after Jan. 27, 2020, and end on Dec. 31, 2020, and would last no longer than 39 weeks for any recipient. The federal government would reimburse each state 100% of any expanded unemployment insurance provided to recipients, along with reasonable administrative fees. The bill ensures that enhanced unemployment isn't considered in the income calculations for participants in Medicaid and the Children's Health Insurance Program (CHIP) Finally, the CARES Act also allows the federal government to reimburse states for the costs of providing expanded unemployment insurance to displaced employees of

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governments and nonprofit organizations through Dec. 31, 2020.

### Rebates and Support for Individuals

The CARES Act provides checks to Americans that can be used against tax liability of \$1,200 per individual (\$2,400 per couple), and \$500 per child through Dec. 31, 2020. Full payments would be allowed for individual incomes up to \$75,000 (\$150,000 per couple) and would phase down as incomes increase above those amounts. Recipients of checks will receive notice from the federal government at their last known address that indicates the method of payment and point of contact at the Internal Revenue Service within 15 days of payments being sent out.

### Tax-Favored Withdrawals from Retirement Accounts and Temporary Waiver of Required Distribution Rules

The package allows tax-favored coronavirus-related withdrawals of up to \$100,000 from retirement accounts. Individuals that take distributions from their retirement accounts for coronavirus-related purposes would not be subject to the 10-percent early withdrawal penalty that would ordinarily apply, and income attributable to such withdrawals would be subject to tax over three years. Moreover, affected individuals would be permitted to contribute the funds to an eligible retirement plan without regard to that year's cap on contributions.

Coronavirus-related distributions from retirement accounts must occur between Jan. 1, 2020, through Dec. 31, 2020. Although the Secretary of the Treasury has the ability to determine additional factors, the bill initially allows to individuals who are diagnosed with coronavirus, a spouse or dependent of someone diagnosed with coronavirus, or someone who has experienced adverse financial consequences due to coronavirus (quarantine, furlough, hour reductions, business closure, lack of childcare, etc.) to take a tax-favored withdrawal.

The bill also waives the required minimum distribution rules for certain defined contribution plans and IRAs for calendar year 2020.

### Charitable Deductions

The CARES Act permits Americans to deduct up to \$300 of charitable contributions in cash to churches and charitable organizations whether they itemize their taxes or not. The bill also suspends the 50 percent of adjusted gross income limitation on deductions for individuals for 2020 and increases the 10 percent limitation on charitable deductions applicable to corporations to 25 percent of taxable income.

### Exclusion for Certain Employer Payments of Student Loans

The CARES Act enables employers to provide a student loan repayment benefit to employees on a tax-free basis. Under the provision, an employer may contribute up to \$5,250 annually toward an employee's student loans, and such payment would be excluded from the employee's income. The

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exclusion applies to student loan payments made by an employer on behalf of an employee after the date of enactment and before Jan. 1, 2021.

### Relief for the Healthcare Sector

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To better support hospitals that are struggling with costs due to the coronavirus, the CARES Act allows the Secretary of Health and Human Services to:

- Make accelerated payments on a periodic or lump sum basis;
- Increase the inpatient Medicare reimbursement by 25%;
- Extend the period allowed for accelerated payment by six months;
- Provide 120 days to reconcile and offset any claims for accelerated payments; and
- Allow at least one year from the day hospitals receive the first accelerated payment to pay any outstanding balances in full.

The CARES Act ensures that personal protective equipment and ancillary medical supplies required to administer drugs, vaccines, medical devices, and diagnostic tests are all included in the Strategic National Stockpile. The bill also boosts funding for the Public Health and Social Services Emergency Fund by \$100 billion to reimburse health care providers enrolled in Medicare and Medicaid that have lost substantial amounts of revenue due to coronavirus. The dollars could be used to build temporary structures, buy medical supplies and equipment, and boost their workforce and surge capacities.

In order to improve access to coronavirus testing, the CARES Act requires health insurance plans to reimburse providers for coronavirus testing at the previously negotiated rate, or through the cash price that is listed on the internet. The package requires each provider of emergency coronavirus tests to list the cash price on the internet. The bill also requires health insurers to cover preventive services like immunizations that will mitigate the spread of coronavirus without cost-sharing from patients.

To better support the nation's health care safety net, the CARES Act provides an additional \$1.32 billion for federally qualified health centers and also extends funding for federally qualified health centers, the National Health Service Corps, the Teaching Health Centers Graduate Medical Education Program through Nov. 30, 2020. The bill delays cuts to hospitals that serve large numbers of low-income patients, known as disproportionate share hospitals, through Nov. 20, 2020. It also ensures that volunteer health care providers aren't liable for harm if they're providing services in response to the coronavirus, and the act or omission occurs:

- During the course of providing health care services;
- In the health care providers' professional capacity as a volunteer;

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- In the course of providing services within their scope of practice, license, registration, or certification; and
- In a good faith belief that the individual being treated needs health care services.

The CARES Act also allows the Secretary of Health and Human Services to temporarily assign members of the National Health Services Corps to sites that are different from their current site of practice. The bill also reinvests in the Health Resources and Services Administration (HRSA) Title VII Health Professions Workforce programs and Title VIII Nursing Workforce programs by extending funding for these key initiatives through 2025. These programs train and expand the ethnic, geographic, and racial diversity of our nation's health workforce.

The package supports access to telehealth services in several ways by allowing individuals with high-deductible health plans to access telehealth services before they've reached their annual deductible – ensuring that telehealth services aren't out of reach due to cost barriers. The CARES Act also allows telehealth reimbursement for federally qualified health centers and rural health clinics when patients are not at the same location as the provider. These reimbursements would be pegged to similar payments for telehealth services under the physician fee schedule, and also would be excluded in the unique payment calculations for federally qualified health centers and rural health clinics. The CARES Act also seeks to boost support for hospitals by temporarily suspending the 2 percent Medicare sequestration cut through Dec. 31, 2020, and also boosting add-on payments for outpatient hospital visits related to coronavirus by 20%.

In an effort to boost access to an eventual coronavirus vaccine among Medicare beneficiaries, the CARES Act includes coverage of the coronavirus vaccine under Medicare Part B. The coronavirus vaccine wouldn't count towards enrollees' deductibles. It also allows Medicare Advantage (Part C) and Medicare Drug (Part D) to obtain 3-month supplies of covered drugs during the coronavirus epidemic.

The CARES Act also makes clarifications to the 6.2% Federal Medicaid Assistance Percentage (FMAP) increase provided to states in Congress' previous coronavirus package. The 2nd coronavirus package prohibits states from receiving the 6.2% FMAP increase if they:

- Make their eligibility standards more restrictive than they were at the beginning of the year (includes waivers);
- Impose a higher premium for enrollees than what was in place at the beginning of the year;
- Fail to allow enrollee participation through the end of a given month when Medicaid coverage stops; or
- Impose cost sharing for coronavirus tests, vaccines, equipment, therapies, etc.

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The CARES Act makes clear that for states where the points above don't apply, they can still receive the enhanced FMAP by:

- Certifying to the Health and Human Services Secretary that they haven't violated the points above; and
- Maintaining the same restrictions on their Medicaid programs that were in place when Congress' 2nd coronavirus package passed on 3/18.

### Relief for Higher Education

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The CARES Act includes funding for the creation of an Education Stabilization Fund, of which \$14 billion is designated for all sectors of higher education, with half going to emergency grants for students and the other half going to institutions. Amounts to institutions are based on a 75/25 formula calculating an institution's Pell Full Time Equivalent (FTE) enrollment and overall FTE enrollment. Students who were enrolled online prior to the coronavirus are not included in the formula. For institutions of higher education, these grants can be used to offset lost revenue, transitioning to distance learning as well as assisting students in need by providing grants for housing, food, course requirements, and technology expenses.

The CARES Act eases a number of current regulations to allow colleges and universities the flexibility to use institutional aid to support undergraduate and graduate students that have unexpected expenses and unmet financial need due to coronavirus. The bill waives the required institutional matching of federal funds for campus-based programs for this school year and next. Institutions can draw down unused work-study funds for supplemental grants to students as well as award additional Supplemental Educational Opportunity Grant (SEOG) funds to students adversely impacted. The bill directs the Department of Education to ensure that both federally subsidized loan amounts and Pell Grants amounts are not counted towards a student's lifetime loan or lifetime Pell eligibility if the student does not complete the semester due to the coronavirus. Requirements to return Pell Grants, federal loan amounts, and other grant assistance if a student withdraws from school are waived for both the student and the institution. The bill allows schools to continue making federal work-study payments to those students unable to fulfill their work-study obligation due to workplace closures. The bill defers payments of current HBCU Capital financing loans during the national emergency period freeing up those funds for HBCUs to address coronavirus efforts.

Of note, this legislation does not include a loan cancellation provision embraced by many, which would have had the federal government paying down a borrower's student loans by \$10,000. Instead, the CARES Act provides

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relief to student borrowers by deferring federal student loan payments, principal and interest until September 30, 2020. The bill expands tax code Section 127 to incentivize employers to implement student loan repayment programs allowing up to \$5,250 in student loan repayments made by the employer on behalf of the employee for 2020. Additionally, the Department of Education will stop collections and the garnishing of wages of those borrowers who are behind on payments for at least the next sixty days.

## FDA Regulation of Medical Products, Including Drugs and Medical Devices

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Title III, Subtitle A of the CARES Act, includes numerous provisions directed at addressing supply shortages of medical products. A few of the highlights are summarized below. Perhaps the most significant change is the amendments to the Food, Drug, and Cosmetic Act to include medical devices in the notification and other requirements for supply shortages that historically have applied only to drugs. Filling this gap should help to mitigate a repeat of shortages in PPE, respirators, and other medical supplies currently experienced during the COVID-19 pandemic. The liability protections granted previously to drugs under the PREP Act of 2005 are now also extended to PPE and other medical devices. This Title also includes a provision that requires manufacturers of drugs, APIs, and devices to develop a risk redundancy management plan.

### Medical Product Supplies

**Strategic National Stockpile.** The existing statutory targeted liability protections for pandemic and epidemic products and security countermeasures are amended to include PPE, ancillary medical supplies, and other applicable supplies.

**Treatment of Respiratory Protective Devices as Covered Countermeasures.** NIOSH-approved respiratory protective devices that the HHS Secretary determines to be a priority for use during a declared public health emergency are included as a covered countermeasure.

### Mitigating Emergency Drug Shortages

**Additional Manufacturer Reporting Requirements.** Manufacture of drugs, API, and any associated medical are required to develop, maintain, and implement a redundancy risk management plan that identifies and evaluates the risk of the drug supply for each establishment in which such drug or API is manufactured. These risk management plans are to be made available to FDA for inspection and copying under the FDA's general inspection authority.

The FDCA provisions pertaining to the FDA's drug establishment listing requirements (21 USC 360(j)) are amended to require registrants to submit an annual report to FDA on the amount of each listed drug that was

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manufactured or otherwise prepared for commercial distribution.

### Preventing Medical Device Shortages

**Discontinuance or Interruption in Medical Device Production.** Manufacturers of a medical device that is (1) critical to public health during a declared public health emergency, or (2) for which FDA determines information on potential supply disruption is needed, are required to comply with certain notification requirements as to discontinuance or interruption in supply. Such notifications are to be communicated to “appropriate organizations,” including healthcare professionals, patient organizations, and supply chain partners. However, HHS has the authority to decline to make this information publicly available if it determines that doing so would adversely affect the public health (e.g., by increasing over the purchase of a product or component parts or otherwise disrupt the availability of medical products to patients). Failure of a manufacturer to comply with these notification requirements may result in public disclosure.

If FDA concludes that there is or likely to be a shortage of a device, FDA is granted the authority to expedite the review of a marketing application for or an inspection related to, a device that could help mitigate or prevent such shortage.

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FDA will establish and maintain a current list of devices for which it determines to be a shortage. Such a list is to be made publicly available (with trade secret and confidential information redacted), and to include the device category, the manufacturer name, the reason for the shortage, and its estimated duration. Similar to the notification requirement, the FDA is given the authority to decline to make this information publicly available if it determines that disclosure would adversely affect the public health.

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