ROPES & GRAY

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INFORMATION & UPDATES

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Additional Insight into the Senate Proposal for the Coronavirus Aid, Relief, and Economic Security Act

*****This legal development is still in progress. We will update this Alert as the Act makes its way through the legislative process.*****

****This Alert supplements the Tax Alert, previously published****

On Thursday night, March 18, 2020, Mitch McConnell introduced into the Senate proposed language for the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), commonly referred to as Phase 3 of the federal government's response to the coronavirus outbreak. The proposed Act builds on the prior two pieces of legislation to expand relief to individuals and business. Among other things, the proposed Act provides changes to tax policy, including authorizing a refund of tax of up to $1,200 per individual and delaying tax filing and payment deadlines for employers and individuals; provides for a $300 billion small business interruption loan program, with maximum loans for eligible businesses capped at $10 million; authorizes the Secretary of Treasury to make or guarantee loans of up to $208 billion to eligible businesses; mandates insurance coverage of coronavirus testing; expands access to telehealth; and provides a number of significant changes to FDA requirements in connection with the prevention or mitigation of life-saving drug shortages. The proposed bill can be found here. The bill is currently being negotiated in the Senate, and must still be approved by the House of Representatives. Negotiations are expected to continue through the weekend.

This Alert addresses the following Divisions of the proposed Act:

- Small Business Interruption Loans (Division A)
- Relief for Individuals, Families, and Businesses (Division B)
- Assistance to Severely Distressed Sectors of the United States Economy (Division C)
- Health Care Response, Health Provisions (Division D, Title I)
- Health Care Response, Labor Provisions (Division D, Title III)

Small Business Interruption Loans (Division A)

Loan Program. The proposed CARES Act expands the Small Business Administration's (SBA) loan program during the covered period (March 1, 2020 to June 30, 2020) to any business with 500 employees or fewer. The maximum loan amount for eligible businesses is $10 million. Loan proceeds may be used for various business purposes, including but not limited to: (i) payroll support (e.g., paid sick, medical or family leave); (ii) employee salaries; (iii) mortgage payments; (iv) rent; (v) utilities; and (vi) other debt obligations that were incurred before the covered period. The loan program is capped at $300 billion.

Loan Forgiveness. The proposed CARES Act provides that any covered loan is eligible for forgiveness in the amount equal to the cost of maintaining payroll during the covered period (subject to certain limitations and reductions).

No Prepayment Penalties. No prepayment penalties will apply to any payments made on or before December 31, 2020 on covered loans.

Grants. The SBA may also grant funds to resource partners (i.e., small business development centers, women's business centers and minority business centers) to enable recipients to provide education, training and advising to small businesses on business practices necessary to address the various issues related to COVID-19.

Relief for Individuals, Families and Businesses (Division B)

Key relief for individuals includes the following:

- *Individual Rebates*: Authorizes a refund of tax for an eligible individual (generally an individual who is not a nonresident alien individual) to the lesser of tax reflected on an individual's tax return or $1,200 per individual ($2,400 for joint return), but not less than $600 per individual ($1,200 for joint return). Taxpayers will receive an additional $500 per child. Limitations include being subject to reduced rebate where AGI exceeds $75,000 per individual ($150,000 for joint return).

- *2019 Filing & Payment Deadline Deferred*: Extension of the April 15, 2020 filing deadline for 2019 to July 15, 2020. Accordingly, 2019 tax payments due on April 15, 2020 would be deferred (with no cap on the amount deferred) until July 15, 2020. Notice 2020-18 issued Friday evening by the Treasury confirms that the IRS will apply these deadline extensions from April 15, 2020 to July 15, 2020 for both filing of 2019 income taxes and payment thereof and that there is no cap on payment amounts deferred to July 15, 2020.

- *2020 Estimated Tax Payments Deferred*: Postponement of estimated tax payments due from the date of enactment until October 15, 2020 (with no cap). In effect, the first three (3) quarterly payments will all be due on October 15.

Key relief for businesses includes the following:

- *Corporations' Estimated Payments Pushed*: Defers corporations' 2020 estimated tax payments until October 15, 2020.

- *Employer Tax Payments Pushed*: Delay of payment of employer payroll taxes (and 50% of self-employment taxes, which is the equivalent of the employer portion) from when the CARES Act is enacted to January 1, 2021. Fifty percent of this deferred amount is paid on December 31, 2021. The remaining 50% is paid on December 31, 2022.

- *NOL Changes*: A net operating loss (NOL) arising in a taxable year beginning after December 31, 2017, and before January 1, 2020, generally can be carried back five years preceding the taxable year of such loss. In addition, the effective date of the "80% NOL limitation" rule enacted in December 2017 is changed to be effective for tax years beginning after December 31, 2020; thereby making 100% of NOLs generally available for offset in 2018, 2019 and 2020.

- *Business Interest Expense Deductions*: Business interest expense deductions can be taken for up to 50% of business income (up from 30%) for 2019 and 2020. For 2020, the business can elect to use 2019 income to determine the limitation amount.

- *Bonus Depreciation*: One hundred percent bonus depreciation now applies to qualified improvement property.

For additional information about tax implications of the proposed CARES Act, see our separate Tax Alert.

Assistance to Severely Distressed Sectors of the United States Economy (Division C)

Under the proposed CARES Act, the Secretary of Treasury is authorized to make or guarantee loans of up to $208 billion to eligible businesses. The proposed CARES Act provides the Secretary of the Treasury broad authority to determine eligibility and set the terms of the loans or guarantees, with the following limitations:

1. *Distribution*: The $208 billion is to be broken out as follows: (i) not more than $50 billion for passenger air carriers; (ii) not more than $8 billion for cargo air carriers; and (iii) not more than $150 billion for other eligible businesses.

2. *Eligible Business*: An eligible business is defined to be an air carrier or a United States business that has incurred losses as a result of the coronavirus such that the continued operations of the business are jeopardized and that has not otherwise applied for or received economic relief in the form of loans or loan guarantees provided under another provision of the CARES Act.

3. *Terms and Conditions*: Loans and loan guarantees may be provided only where (i) the obligor is an eligible business for which credit is not reasonably available at the time of the transaction; (ii) the intended obligation would be "prudently incurred"; and (iii) the loan is sufficiently secured. In addition, the rate of any loan shall not be less than the average yield on outstanding marketable obligations of the United States of comparable maturities, and the Secretary should, to the extent practicable, ensure that the government is fairly compensated for the loans and loan guarantees. In connection with any loan, the Secretary is also authorized to enter into contracts providing for participation in gains of the eligible business or its securityholders through warrants, stock options, common or preferred stock or other equity instruments.

4. *Limitations on Employee Compensation*: To receive a loan under this provision, the eligible business must enter into a legally binding agreement committing that, for two years (from March 1, 2020 to March 1, 2022), any officer or employee who received total compensation in 2019 over $425,000 (i) will not receive total compensation during any 12 months of the two-year period that exceeds the amount received in 2019, and (ii) will not receive termination benefits (e.g., severance pay) that exceed twice the compensation received in 2019. Total compensation is defined to include salary, bonus, awards of stock, and other financial benefits provided by the eligible business. This provision excludes employees whose compensation is determined by a collective bargaining agreement entered into prior to March 1, 2020.

The Secretary is instructed to publish procedures for applications and minimum requirements no later than 10 days after enactment of the CARES Act.

Health Care Response, Health Provisions (Division D, Title I)

1. Health Care Provisions

Coverage of COVID-19 Testing and Vaccines: Requires health plans and health insurance issuers offering group or individual coverage to cover, without any cost-sharing (including deductibles, copayments, and coinsurance) or prior authorization requirements: (i) in vitro diagnostic products that detect COVID-19, including tests without an Emergency Use Authorization ("EUA") issued by FDA (*see* FDA Provisions below for more information about EUAs); (ii) items and services furnished to an individual during health care provider office visits that relate to furnishing or administering a diagnostic, including the evaluation of such individual; and (iii) "qualifying" COVID-19 preventive services, such as vaccines. Requires health care providers to advertise the dollar amount of a COVID-19 diagnostic test on a public website.

Expanded Funding of Federal Health Centers and Rural Health Networks: Appropriates $1.32 billion for FY 2020 to federal Health Centers designated under Section 330 of the Public Health Service Act, that provide care primarily to low-income individuals, for the prevention, diagnosis, and treatment of COVID-19. Provides the Health Resources and Services Administration with enhanced flexibility to make grants supporting care providers in rural areas providing basic healthcare services.

Expanded Access to Telehealth: Authorizes $29 million each year from FY 2021 to 2025 for the National Telehealth Resource Center Program, which provides grants to support telehealth in rural areas, frontier communities, and medically underserved areas. Provides a safe harbor for high-deductible health plans to provide telehealth and other remote care services and excludes telehealth and other remote care services from being considered a health plan that would disqualify a person for eligibility for a Health Savings Account ("HSA"). Expands Medicare reimbursement for telehealth services furnished by federally qualified health centers and rural health clinics and adds a temporary waiver of requirement for face-to-face visits between home dialysis patients and physicians. Eliminates the requirement in the earlier Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 that a physician or other professional must have treated the patient in the past three years to be payable by Medicare.

Other HSA Provisions: Provides for revisions to the treatment of direct primary care service arrangements under Section 223(c)(1) of the Internal Revenue Code, which governs HSAs. In part, excludes direct primary care services as a health plan that disqualifies a person for eligibility for an HSA and specifies payments for such services are a qualified medical expense. Expands the definition of qualified medical expenses for qualified HSAs, medical savings accounts and health flexible spending accounts.

Expanded Powers of Midlevel Practitioners to Order Medicare Home Health Services: Provides that a nurse practitioner, a clinical nurse specialist, or a physician assistant under the supervision of a physician may certify home health services for payment by Medicare.

HIPAA Guidance Governing Disclosure in a Public Health Emergency and Substance Use Disorder Privacy Provisions: Directs the Secretary of Health and Human Services ("HHS") to issue guidance, within 180 days after the date of enactment, on the sharing of patient protected health information and applicable policies, during the COVID-19 public health emergency. Provides for changes to the federal statute governing disclosure of substance use disorder records (42 U.S.C. 290dd-2), including privacy practices, disclosure requirements, disclosure of de-identified information to public authorities, and breach-notification requirements.

Limitation on Liability for Volunteer Health Care Professionals: Limits the liability of health care professionals acting in good faith during the COVID-19 emergency response so long as the health care professional is providing health care services in a volunteer capacity, and the services the health care professional provides are in response to COVID-19 and are within the scope of the health care professional's license, subject to limited exceptions.

Medicare Payment Relief: Temporarily suspends Medicare sequestration cuts between May 1, 2020 and December 31, 2020. Increases the weighting factor for each diagnosis-related group under the Medicare inpatient prospective payment system by 15 percent for discharges during the emergency period with a primary or secondary diagnosis of COVID-19. Prevents scheduled decreases in payment amounts for durable medical equipment during the emergency period.

Provider Technology-Enabled Learning Support: Provides federal reimbursement to states in providing, as medical assistance, a technology-enabled collaborative learning and capacity-building model to be used by providers for purposes of training health care professionals in protocols to respond to a public health emergency.

2. FDA Regulatory Provisions

Shortages of Life-Saving Drugs: Provides a number of significant changes to FDA requirements in connection with the prevention or mitigation of life-saving drug shortages. Amends the section of the Food, Drug, and Cosmetic Act ("FDCA") that grants FDA discretion to expedite drug inspections and reviews in the event of a shortage of life-saving drugs to require that FDA, when appropriate, not only expedite but also prioritize such inspections and drug reviews in an effort to mitigate or prevent such shortages. Expands the scope of existing life-saving drug shortage notification requirements by including "any such drug that is critical to the public health during a public health emergency determined under section 319 of the Public Health Service Act" and by subjecting manufacturers of active pharmaceutical ingredients ("API") for drugs covered by the notification requirement to the shortage notification requirement. Lists the information that must be included in a shortage notification report. Imposes a new requirement on manufacturers of life-saving drugs subject to the provision—including manufacturers of API for such drugs—to maintain contingency and redundancy plans as appropriate for each establishment where such drugs and API are manufactured. Requires FDA to transmit a report of drugs on the drug shortage list to the Centers for Medicare and Medicaid Services ("CMS") administrator not later than 180 days after the enactment of the requirement, and every 90 days thereafter. Requires that when FDA conducts inspections of facilities that manufacture approved drugs for which a shortage notification has been provided to the agency within the last five years, or that are listed on FDA's required drug shortage list, a copy of the inspection report is provided promptly to the appropriate agency offices with expertise on drug shortages. Requires FDA drug shortage experts to ensure timely and effective coordination for the review and presentation of coordinated feedback regarding the report and any corrective or preventive actions after considering the "systematic benefits and risks to public health, patient safety, the drug supply and drug supply chain, and timely patient access to such drugs."

Life-Saving Drug Shortage Reports to Congress and Other Agencies: Within two years of enactment of the legislation, requires the Government Accountability Office ("GAO") to issue a report to several agencies examining the FDA's intra-agency coordination, communication, and decision-making in assessing drug shortage risks, and taking corrective action. Requires that the HHS Secretary develop and submit a report to the Senate HELP Committee and House Energy and Commerce Committee containing recommendations for market-based incentives or other appropriate mechanisms sufficient to encourage the manufacture of drugs in shortage or at risk of shortage and how the FDA Emerging Technology Program can help facilitate creating or upgrading existing technologies to address drug shortage challenges and promote modern, reliable manufacturing strategies.

Safe Harbor Provision for Communications about Products Subject to Emergency Use Authorization: Provides a new safe harbor regarding the communication of information about drugs and devices subject to EUA provided or distributed to a health care provider. The safe harbor prevents such information from being considered evidence that such drug or device is misbranded for bearing false or misleading labeling or because its labeling lacks adequate directions for use under sections 502(a) and 502(f) of the FDCA. It also prevents such information from being used as evidence of a violation of premarket review provisions in the FDCA and Public Health Services Act or of a violation of the EAU provisions of the FDCA. However, for a drug or device to be eligible for this safe harbor, the information provided can be neither false nor misleading, must be accompanied by an appropriate disclaimer, and must be based on competent and reliable scientific evidence. The provision includes specific requirements for the disclaimer and significant detail regarding what would constitute "competent and reliable scientific evidence."

Preventing Essential Medical Device Shortages: Adds a new section to the FDCA requiring advance notification of shortage by device manufacturers, similar to the requirement for manufacturers of life-saving drugs, for any device that is "critical to public health" during an emergency, including devices that are "life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery" or "for which the Secretary determines that information on potential meaningful supply disruptions of such device is needed during, or in advance of, a public health emergency" and the reasons for such shortages. Requires the Secretary of Health and Human Services (HHS Secretary) to distribute information on such shortages to appropriate organizations, unless the HHS Secretary determines that disclosure of such information would adversely affect the public health, such as by increasing the possibility of unnecessary over purchase of product or other disruption of the availability of medical products to patients. Authorizes (but does not require) the HHS Secretary to prioritize and expedite review of submissions, notifications, or inspections/re-inspections if the HHS Secretary concludes there is or is likely to be a shortage of a device based on the required notification. Requires the establishment and maintenance of a publicly available device shortage list, though information is subject to exceptions for public health or trade secret/confidential information.

Essential Device Shortage Reports to Congress and Other Agencies: Just as in the context of life-saving drug shortages, the proposed legislation would require a device-specific GAO report on intra-agency coordination in connection with shortages. In addition, the Comptroller General of the United States will be required to submit to the Senate HELP Committee and the House Energy and Commerce Committee a report examining the FDA's intra-agency coordination, communication, and decision-making in assessing device shortages and risks associated with the supply of devices, and any efforts by FDA to mitigate any device shortages or take corrective actions.

Emergency Use of Laboratory Developed Tests ("LDTs"): Grants legal marketing status for in vitro diagnostics developed to diagnose COVID-19, for the period of time that the COVID-19 public health emergency is in place, under three conditions. Marketing of tests would be legal if the tests are (1) developed in a state that has notified the HHS Secretary of its intention to review such tests, (2) developed in a lab with a high-complexity testing certificate, and the developer of such test is pursuing an emergency use authorization from FDA and provides updates to the HHS Secretary on efforts to pursue such authorization; validates such test prior to use; notifies the HHS Secretary of the assay validation; and includes a required statement regarding the lack of FDA review of the test, or (3) an in vitro diagnostic test (as opposed to an LDT) for which the developer of such test meets the requirements in section (2). When the COVID-19-related public health emergency terminates, the legislation also requires the HHS Secretary to consult with the developer of any test subject to this provision for the diagnosis of COVID-19 regarding the appropriate disposition of such test to ensure that authorization of any in vitro diagnostic test under this section shall continue to be effective, to provide for continued use of such product to prevent or detect COVID-19.

Innovation Provisions: Contains provisions designed to encourage innovation, including a provision that removes a FDCA sunset provision for a priority review program designed to encourage treatments for agents that present national security threats. Provides a pathway for expedited development and review of certain new animal drugs if preliminary clinical evidence indicates that the new animal drug has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in humans.

Treatment of Respiratory Protective Devices as Covered Countermeasures: Amends the definition of "covered countermeasures" under the Public Health Service Act to include respiratory protective devices approved by the National Institute for Occupational Safety and that the Secretary determines to be a priority for use during a public health emergency.

Finance-Related Provisions: Provides for studies regarding barriers for "DISARM Anti-Microbial Drugs," as defined under the Social Security Act ("SSA"). Provides that the Comptroller General shall consult with the director of the National Institutes of Health ("NIH"), FDA Commissioner, CMS Administrator, and CDC Director to conduct studies to identify and examine barriers that prevent the development of drugs or biological products that are designated as DISARM microbial drugs.

Health Care Response, Labor Provisions (Division D, Title III)

Limitations on Employer Paid Sick Leave Obligations: An employer's requirement to provide paid leave with respect to any individual employee expires the earlier of: (i) the time when the employer has paid for sick leave for an equivalent of 80 hours of work; or (ii) upon that employee's return to work after taking paid leave. In other words, Emergency Paid Sick Leave must be used all at once, not intermittently.

Paid Leave for Rehired Employees: Recently rehired employees are now eligible for leave under the Emergency Family and Medical Leave Expansion Act ("EFMLEA").

Secretary of Labor Exclusion for Small Businesses: Although the internal cross-references are not entirely accurate in the draft legislation, the CARES Act allows the Secretary of Labor to exempt employers of fewer than 50 employees from providing emergency paid sick leave to employees caring for an individual who is quarantined or self-quarantined or a child whose school closed or other caregiver has become unavailable due to coronavirus, but does not extent this waiver authority to other uses of emergency paid sick leave.