

The background is a teal gradient with faint, semi-transparent images of chemical structures and laboratory glassware, including a pipette tip and test tubes.

COVID-19 U.S. TOOLKIT

for UK/European private technology, life sciences, and growth companies

April 2020

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This presentation does not constitute legal advice and should not be relied upon for business or legal decisions.

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*For up to date alerts
and advisories, see
Wilson Sonsini's
COVID-19 Client
Advisory Resource*

1. Continuing Business Operations

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Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce

Federal Orders

- As of April 8, 2020, the federal government has not issued a mandatory shelter in place order.
 - However, the federal government has issued guidance on what constitutes essential services, which in large part serves as a base for the various mandatory state orders discussed below. The federal guidance can be reviewed at the following link: <https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce>.
 - Additionally, the CDC and OSHA have issued interim guidance for businesses and employers to plan and respond to COVID-19, which can be found at the following links: <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html> and <https://www.osha.gov/Publications/OSHA3990.pdf>.

Delaware Law Implications Applicable to Board Members and Officers

- Given the prevalence of shelter in place orders, board members and officers must be sure to discharge their fiduciary duties as it relates to knowing violations of such orders. It is important to remember that a director or officer engaging in a knowing violation of the law breaches his or her fiduciary duties.
- Under Delaware's Caremark standard, a board of directors has to have reasonable procedures in place to (1) prevent breaking the law and (2) ensure directors are adequately informed of the risks that a law may be broken.

Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce (continued)

Sample State Orders (Note: Be sure to review the relevant state government websites for your U.S. business)

- **California:** On March 19, 2020, California ordered all individuals to stay home or at their place of residence, except as needed to maintain continuity of operation of the federal critical infrastructure sectors.
 - Federal critical infrastructure sectors include healthcare and public health, emergency services, food and agriculture, energy, water and wastewater, transportation and logistics, communications and information technology, community-based government operations and essential functions, critical manufacturing, hazardous materials, financial services, chemical, and defense industrial base.
 - The following link provides further information on sector profiles and essential workforce:
<https://covid19.ca.gov/img/EssentialCriticalInfrastructureWorkers.pdf>.
 - Note that certain local jurisdictions have put additional orders in place which may compete with state orders. Guidance from California is to follow the most restrictive order applicable.
 - Revised Bay Area Shelter-in-Place Orders of March 31, 2020: <https://www.wsgr.com/en/insights/update-bay-area-counties-tighten-orders-regarding-sheltering-in-place.html>
- **Massachusetts:** On March 23, 2020, Governor Charlie Baker issued an emergency order requiring all businesses and organizations that do not provide "COVID-19 Essential Services" to close their physical workplaces and facilities to workers, customers, and the public.
 - The list of Essential Services is based largely off the federal guidelines. The following link provides further information on Essential Services for Massachusetts: <https://www.mass.gov/doc/covid-19-essential-services/download>.
 - The Governor specifically stated that manufacturers of medical products and pharmaceutical companies developing treatments for COVID-19 and other diseases will continue to operate, and are exempt as essential business. After the order was released, Baker Administration officials clarified to that all biopharma R&D is essential and exempt.
- **New York:** On March 22, 2020, Governor Cuomo announced the "New York State on PAUSE" executive order, requiring all non-essential workers to work from home until further notice.
 - "Essential Business" means essential health care operations, infrastructure, manufacturing, retail, certain services, news media, financial institutions, providers of basic necessities to economically disadvantaged populations, construction, defense, safety and sanity operations, and vendors that provide logistics and technology support.
 - The following link provides further information on essential businesses and to request designation as such:
<https://www.governor.ny.gov/news/governor-cuomo-issues-guidance-essential-services-under-new-york-state-pause-executive-order>.

Continuing Business Operations

Complying with Federal and State Guidelines on Essential Critical Infrastructure Workforce

■ OSHA: Duty To Ensure A Safe Workplace

- OSHA covers most private sector employers and employees in the U.S.
- OSHA: Employers must furnish to each employee “employment and a place of employment, which are free from recognized hazards that are causing or are likely to cause death or serious physical harm.”
- CDC recommendations to prevent workplace exposure and planning considerations:
 - Perform frequent environmental cleaning
 - Support good hygiene practices (i.e., hand washing and respiratory etiquette)
 - Implement social distancing (see below)
 - Emphasize staying home when sick
 - Discourage use of others’ equipment and workspaces.
 - Be prepared to implement Workplace Emergency Readiness Plan

■ Social Distancing

- Social Distancing means reducing the frequency, proximity, and duration of contact between people (both employees and customers) to reduce the chances of spreading the virus from person to person
 - Use videoconferencing and email to reduce in-person, non-essential meetings
 - Reduce or restrict social gatherings
 - Cease non-essential visits from non-employees at the offices
 - Implement telecommuting where possible
 - Staggered shifts for employees coming into the worksite

Continuing Business Operations

Complying with Federal and State Guidelines Regarding Telecommuting Policies

■ Telecommuting

- Considerations for employers who decide to encourage or require telecommuting to minimize the risks of employees contracting COVID-19:
 - Keeping track of hours worked by non-exempt employees and ensuring compliance with wage and hour laws, such as overtime and meal and rest breaks
 - Employee accessibility and productivity
 - Protecting company confidential information
 - Employee’s use of home computers and other personal devices
 - Network safety – VPN or other encrypted link to home office
 - Recovering company property and information when employees resume working at the office or if employment terminates
 - Are employees responsible for injuries occurring at home?
 - Do federal, state, or local leave laws apply?
- If an employee asks to telecommute, does an employer have to permit employees to telecommute?
 - Review your policies & use common sense
 - The federal Americans with Disability Act requires employers to provide reasonable accommodations to a qualified individual with a disability to enable the individual to perform the essential functions of the job
 - A “disability” is “a physical or mental impairment that substantially limits one or more major life activities”
 - Employees who contract COVID-19 may or may not be seriously ill long enough to substantially limit a major life activity
 - A sick employee may claim that an employer regarded him or her as having a disability, which may form the basis for a discrimination claim under the ADA (although no accommodation requirement)
 - A serious case of COVID-19 could be covered under more expansive state or local laws, such as in New York and California

Continuing Business Operations

Additional U.S. Federal and State Resources

■ U.S. Federal COVID-19 Resource Sites

- <https://www.coronavirus.gov/>
- <https://www.usa.gov/coronavirus>

■ U.S. Centers for Disease Control and Prevention (CDC) COVID-19 Guidance

- <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

■ U.S. State Economic Development Organizations

- <https://www.selectusa.gov/State-Investment-Officials>

■ U.S. Local Economic Development Organizations

- <https://ecodevdirectory.com/listings-category/north-america/united-states/>

2. Employee Matters

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Employee Matters

Family and Sick Leave

■ Emergency Family Medical Leave (EFMLA)

- Employers with fewer than 500 employees must provide eligible employees with up to 12 weeks of leave:
 - If the employee is unable to work (or telework) due to the need to care for the employee's son or daughter under 18 years of age if the child's school or place of care has been closed, or the child care provider is unavailable due to COVID-19.
 - Employees are eligible for leave if they have worked at least 30 days for their employer.
- The first 10 days of leave are unpaid, but employees may elect to substitute any of their accrued vacation, personal, medical, or sick leave for such time.
 - The remaining EFMLA days shall be paid by the employer (who may be entitled to receive corresponding tax credits).
 - Employees are entitled to payment that is at least two-thirds of an employee's regular rate of pay for the number of hours the employee would otherwise be normally scheduled to work. The payments are capped at \$200 per day and \$10,000 in the aggregate.
- Employers are generally required to restore eligible employees to the position they previously held (or its equivalent) following their return from leave. There are specific exceptions for employers with fewer than 25 employees.

■ Emergency Paid Sick Leave Act

- Employers with fewer than 500 employees must provide eligible employees 10 days of paid sick leave if the employee is quarantined due to COVID-19 or caring for someone quarantined due to COVID-19, the employee is experiencing symptoms of COVID-19 and is seeking medical diagnosis, or the employee is caring for a child, if the child's school or child care facility has been closed or the child's care provider is unavailable because of COVID-19 precautions.
- Pay for employees taking leave due to their own medical condition is calculated based on the employee's regular rate, but capped at \$511 per day and \$5,110 total. Pay for employees acting as a caregiver for a family member is calculated based on two-thirds of the employee's regular rate, but capped at \$200 per day and \$2,000 total.
- The Act also prohibits employers from discharging, disciplining, or otherwise discriminating against any employee who takes sick leave, or has filed any complaint relating to the Act (or participates in any such proceeding).

Employee Matters

Sick Leave (Continued)

■ New York Paid Sick Leave (Note: Several other states have recently passed analogous laws)

- New York State recently expanded the state's Paid Sick Leave Law to provide job protection and pay for New Yorkers quarantined as a result of the COVID-19.
- The following provisions took effect as of March 18 and apply to all private employers:
 - Employers with 100 or more employees as of January 1, 2020: Must provide at least fourteen (14) days of paid sick leave for employees who are subject to a mandatory or precautionary order of quarantine or isolation due to COVID-19 issued by the state of New York, the department of health, local board of health, or any governmental entity duly authorized to issue such order ("Quarantined Employees").
 - Employers with 11 to 99 employees as of January 1, 2020: Must provide at least five days of paid sick leave for Quarantined Employees. After the five days of paid sick leave, Quarantined Employees are eligible to receive paid family leave and disability benefits starting as of the first full day of the unpaid period of a mandatory quarantine. An employee may collect up to \$840.70 in paid family leave and \$2,043.92 in disability benefits per week during the period of unpaid leave.
 - Employers with ten or fewer employees as of January 1, 2020 (> \$1,000,000 in net income): Must provide the same benefits as those described directly above for employers with 11 to 99 employees. For purposes of this statute, an employer's net income is measured based on the previous tax year.
 - Employers with ten or fewer employees as of January 1, 2020 (< \$1,000,000 in net income): Must provide unpaid sick leave for Quarantined Employees. The Quarantined Employees are eligible to receive paid family leave and disability benefits starting as of the first full day of the unpaid period of a mandatory quarantine. An employee may collect up to \$840.70 in paid family leave and \$2,043.92 in disability benefits per week during the period of unpaid leave.
- **Right to Reinstatement**: Upon return to work, Quarantined Employees must be restored to the position they held prior to any leave taken under this law. No employer may discharge, threaten, penalize, or in any other manner discriminate or retaliate against an employee for taking this leave.

Employee Matters

Salary Reduction Considerations

- **Many companies are considering decreasing salaries to preserve cash. This raises some important considerations:**
 - **Is the arrangement a deferral of salary or a temporary salary reduction? What's the difference?**
 - A deferral of compensation provides an employee (usually limited to executives) with the opportunity to be paid their earned salary (and sometimes bonus) at a later date. This amount is treated as a liability that the company would be required to pay in the future.
 - A temporary salary reduction involves an employee (usually an executive or other highly paid employees) foregoing some portion of their base salary. These amounts are not earned and there is no contractual right for the employee to be paid these amounts in the future.

- **Are salary deferrals more difficult to implement than a temporary salary reduction?**
 - If the arrangement is a salary deferral, then care must be taken to defer the salary in compliance with Section 409A of the U.S. Tax Code. Failure to do so would result in negative tax consequences to the employee (a 20% federal penalty tax, a 5% penalty tax for employees subject to taxation in California, and penalties and interest on top of the employee's regular taxes).
 - Compliance with Section 409A can be restrictive and substantially increase the administration of the arrangement.

- **Due to the complexities of Section 409A, we expect most companies to choose to avoid structuring the arrangement as deferred compensation. Accordingly, the remainder of the considerations discussed on the following slides assume that the arrangement would be structured to be a temporary salary reduction and not a deferral of compensation**

Employee Matters

Salary Reduction Considerations (continued)

■ Will anything be provided in exchange for the salary reduction?

- Companies often want to provide some sort of alternative compensation for reducing salaries. For instance, we often see companies provide for an opportunity to earn a bonus or grant a stock option or other equity award in recognition of the reduced salary
- Any additional arrangement should be structured to comply with tax laws, in particular Section 409A
 - For instance, if the company wanted to continue the salary reduction through a qualified financing event and pay a bonus to the employee upon completion of the financing, the employee should be required to continue employment through the financing event in order to earn the bonus, with the bonus paid shortly after that.
 - For a stock option grant, consider the following:
 - How will the number of shares be calculated? Will it be based on aggregate base salary reduction/FMV or some other formula?
 - Will the stock option be subject to vesting? If so, what will be the vesting schedule?
 - The exercise price should be no less than FMV on the grant date. Consider whether the valuation is current and can continue to be relied upon to establish the FMV of the common stock.

■ Will the salary reduction be forced or elective?

- Employers generally can adjust the compensation of at-will employees on a go-forward basis without their consent, subject to certain exceptions under applicable laws and contractual rights on behalf of the employees.
- If the reduction is to be elective, then the company must consider the tax consequences of doing so. In particular, this election process could result in constructive receipt of the forgone compensation and could potentially trigger penalty taxes under Section 409A.
- As a result, the general preference is that these arrangements be structured as being mandated by the company and not providing a true election opportunity for the employee.

Employee Matters

Salary Reduction Considerations (continued) / Mass Layoffs

■ Additional Considerations

- Confirm whether approval of the Board of Directors and/or Compensation Committee would be required
 - We would expect the Board of Directors and/or the Compensation Committee to approve any arrangement for executives officers even if not technically required.
- Confirm the salary reduction does not require consent under an employee’s employment agreement or applicable law.
- Review “Good Reason” rights and obtain a waiver from each employee if needed to avoid triggering a right to resign and receive severance benefits.
- Confirm whether the intent is for the reduced salary to apply when calculating annual bonus and severance amounts.
- If known, be clear as to when the base salary will resume (and at what amount).
- Depending on the amount of the salary reduction, confirm that the employees will be eligible to participate in the company’s benefit plans and will continue to receive compensation to make any contributions.
- Assess whether reduced salaries violate minimum wage laws.
- Note that commissions that have been earned generally cannot be reduced or deferred.

■ WARN Act / Mass Layoffs

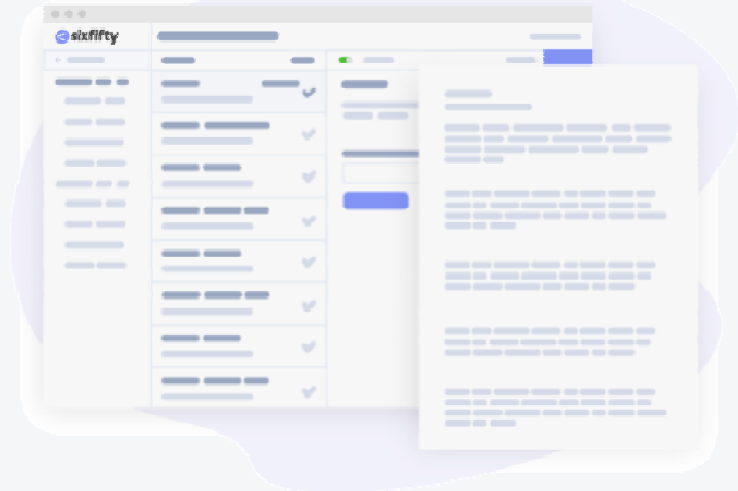
- If layoffs or reduction of hours are being considered for 50 or more U.S. employees, consult with U.S. employment counsel regarding potential implications under the federal Worker Adjustment and Retraining Notification (WARN) Act and state analogues.
 - More on the federal WARN Act: <https://www.dol.gov/agencies/eta/layoffs/warn>

Employee Matters

Wilson Sonsini / SixFifty COVID-19 Digital Tools for U.S. Employee Matters

- Free resource to organize and solve COVID-19-related U.S. employment issues
- Allow employees to confidentially report COVID-19 exposure
- Generate customized COVID-19 employment policies, including:
 - COVID-19 Extended Sick Leave Policy
 - COVID-19 Remote Work Policy
 - COVID-19 Travel Policy
 - COVID-19 Reimbursement Policy

More here: <https://www.sixfifty.com/solutions/hr/covid/>



SixFifty's policies cover extended sick leave, remote work, travel, and reimbursements.

Employee Matters

Additional Resources

- [Employers Should Be Mindful of New Employment Law Risks Created by COVID-19](#), Wilson Sonsini
- [COVID-19 Employment Law Update: What Employers Need to Know About New Federal Legislation Providing for Emergency Paid Leaves](#), Wilson Sonsini
- [Employer Readiness For Issues Arising From The Coronavirus 2.0](#), Wilson Sonsini
- [Coronavirus: Business Interruption and Employment Law Considerations](#), Wilson Sonsini
- [CARES Act Executive Compensation Provisions](#), Wilson Sonsini

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Employers Should Be Mindful of Law Risks Created by COVID-19

ALERTS
April 8, 2020

The COVID-19 pandemic has quickly led to stay-at-home direct requirements, and new legislation. These developments change governing the employment relationship seemingly overnight. A stay-at-home order, many businesses are having to consider vs workforce, including furloughs, pay cuts, and reductions in how as they plan for employees' return to work in the office and the operations over time. We call attention to five areas of potential

The legal implications of various cost-cutting measures.

As businesses pause or contract their operations, they also along with the various options for lowering their payroll of Act triggers, wage and hour law requirements, the impact participating in benefit plan and vesting in equity, and on programs of whether length, furloughs, and reductions in: federal or state WFLSA Act, the rules surrounding the use the standards for maintaining exempt status, among other whether any tax relief or loans may be available under the them to avoid implementing cost-cutting measures in the 4 programs are summarized in Wilson Sonsini's tax relief al

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COVID-19 Employment Law Update: What Employers Need to Know About New Federal Legislation Providing for Emergency Paid L

ALERTS
March 19, 2020

On March 18, 2020, President Trump signed the Families Fi It is one of several federal government efforts to stimulate the individuals and families being caused by the COVID-19 virus \$1 billion stimulus for unemployment insurance benefit pay the Act includes the Emergency Family Medical Leave and I Paid Sick Leave Act (FMLA), both of which provide employee related to the COVID-19 pandemic. The Act, along with emy leave, will become effective on or after April 1, 2020. The 2020.

Emergency Family Medical Leave and Expanded Act

U.S. employees with fewer than 200 employees' team permit protected leave under the Family and Medical Leave Act of: daughter under 18 years of age - if (a) self or spouse of provider - is unavailable, due to a public health emergency; (b) necessary due to a need for such leave; (c) public health emergency COVID-19 declared by a Federal, State, or local authority." If conclusions that "the COVID-19 outbreak is the United St

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Coronavirus: Business Int Law Consideration

Speaking Engagements

Wednesday, March 25, 2020

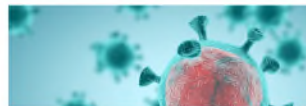
Webinar

ADD TO CALENDAR

Join Wilson Sonsini partner Marina Tzafaris and business interruption insurance and claims case most common:

CONTACTS
Lori Dwyer
lrdwyer@wsg.com

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CARES Act Executive Compens

Speaking Engagements

Wednesday, March 25, 2020

Webinar

The Economic Recovery Act, Relief, and Economic Stimulus and relief programs to employees negatively impacted by CO requirements and may impose limits on employee compensation participate in the program. This alert discusses those program-based payroll tax relief provided under the CARES Act.

Exchange Stabilization Fund Loans

Are limits imposed on employee compensation paid by U.S. Treasury's Exchange Stabilization Fund under Section

Yes. The compensation of highly compensated employees or companies that access loans under Section 4003 of the CARES

These compensation limitations will apply to companies p

Screen Leading Program. For more information on this new

Screen Leading Program Announcement.

Which employees will be limited in their compensation

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EMPLOYER READINESS FOR ISSUES ARISING FROM THE CORONAVIRUS 2.0

Overview Speaker(s) Credit

Following up to our earlier webinar on March 3rd, the spread of the Coronavirus continues to raise a number of issues for employers, including how to handle a mandatory telecommuting situation, take extended sick leave, the ability to require assurances as to the state of employees' health or potential exposure to the virus, and safety and emergency action plans.

Please join Wilson Sonsini and SixFifty for a briefing to identify the employment-related issues that employers should be considering, and continue the conversation about how to address those issues.

Click here the following link for Wilson Sonsini's COVID-19 Client Advisory Resource to assist in navigating through these challenging times: <https://www.wsg.com/en/services/practice-areas/COVID-19.html#overview>

Seminar Information

Seminar Date: March 19, 2020

Products

Streaming + MP4 Download
This Seminar is presented free of charge.

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3. Coronavirus Aid, Relief, and Economic Security Act (CARES Act)

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CARES Act

Executive Summary

On March 27, 2020, the President signed the CARES Act, a \$2 trillion stimulus package thought to be the largest in U.S. history.

The following executive summary provides an overview of the provisions of the CARES Act that could most benefit the technology and life sciences industries.

Executive Summary		
Near-Term Relief		
For companies		
Provision	Effect	Limitations
Employee Retention Tax Credit	A company subject to closure due to COVID-19 orders or that experiences a significant decline in gross receipts may take a refundable tax credit against the 6.2 percent Social Security payroll tax in the amount of 50 percent of up to \$10,000 of wages paid to an employee (giving a maximum credit of \$5,000 per employee) after March 12, 2020 and before January 1, 2021.	SBA PPP Loan recipients are ineligible for this credit (see below). Companies with more than 100 employees are eligible for the credit only for wages paid to employees who are not providing services due to closure or a significant decline in gross receipts.
Payroll Tax Deferral	A company may defer deposit and payment of the 6.2 percent Social Security payroll tax for the remainder of 2020 beginning March 27, 2020: 50 percent deferred until December 31, 2021, and the remaining 50 percent deferred until December 31, 2022.	Companies that have indebtedness forgiven under the SBA PPP (see below) or other comparable loans provided by newly participating financial institutions under the CARES Act will be ineligible for this deferral.
Net Operating Loss Relaxation	Temporarily relaxes certain limitations on the use and carryback of net operating losses (NOLs).	
For individuals		
Provision	Effect	Limitations
Unemployment Insurance Expansion	Temporarily expands eligibility and amount of unemployment insurance.	
Individual Tax Credits	Tax credit in 2020 of \$1,200 (\$2,400 for joint filers) and \$500 per child under the age of 17.	Credit is phased-out for taxpayers with adjusted gross incomes in excess of \$75,000, or \$112,500 for heads of households, and \$150,000 for joint filers.

CARES Act

Executive Summary (cont'd)

Medium-Term Relief		
For companies		
Provision	Effect	Limitations
SBA Paycheck Protection Program (PPP) Loans	<p>\$349 billion allocated for low interest, no-fee loans equal to the lesser of \$10 million and 2.5 times the borrower's monthly U.S. payroll costs as measured over the prior 12 months made by lenders in the SBA's Section 7(a) loan program and other lenders approved by the SBA to qualifying small businesses; loans may be partially forgiven in certain circumstances.</p> <p>Recipients should apply with lenders approved by SBA to provide Section 7(a) loans.</p> <p>At present, companies that have engaged in or plan to pursue layoffs are not per se excluded from PPP, but changes in number of employees can impact the extent of the loan <u>forgiveness</u>, to be describe in a subsequent client alert.</p>	<p>Generally limited to "small business concerns" under a slightly modified version of existing SBA rules, and affiliation aspects of those rules may make many startups that have received venture capital or other investments ineligible without additional relaxation of such rules.</p> <p>Companies that receive such loans are ineligible for employee retention tax credits, and companies that have such loans forgiven are ineligible for the payroll tax deferral described above.</p>
SBA Economic Injury Disaster Loans (EIDL)	<p>Expands existing SBA Economic Injury Disaster Loan (EIDL) program under Section 7(b)(2) and allocates \$10 billion for related SBA grants, whereby recipients can receive up to \$2 million in loans for working capital and ordinary expenditures, based on economic injury from COVID-19. Recipients should apply directly with the SBA.</p> <p>EIDL Applicants may eligible for Emergency IDL Grants up to \$10,000.</p>	<p>Similar limitations as SBA PPP Loans, other than with respect to tax credits and deferral.</p>
Economic Stabilization Measures	<p>500 billion allocated for loans, loan guarantees, and other investments to support eligible businesses, states and municipalities, including emergency relief for qualifying medium-size businesses (500 - 10,000 employees).</p>	<p>Because regulations regarding these programs are yet to be adopted, the details about these programs are currently unknown.</p> <p>Borrowers under these programs may be subject to restrictions, such as restrictions related to equity buybacks, dividend payments, executive compensation, and workforce retention.</p>

CARES Act

Loan Assistance Programs

- Under the CARES Act, small- to medium-sized businesses may qualify for three new loan assistance programs designed to help offset some of the economic pain caused by the COVID-19 pandemic.
 - **Expanded SBA Economic Injury Disaster Loan Assistance (EIDL):** The Coronavirus Preparedness and Response Supplemental Appropriations Act enacted on March 6, 2020 (commonly referred to as the “first phase” of the U.S. government’s legislative responses to the COVID-19 pandemic), together with the CARES Act, expand the existing U.S. Small Business Administration (SBA) Economic Injury Disaster Loan Assistance (EIDL) program in response to the COVID-19 emergency. Under the expanded EIDL program, the SBA may provide qualifying businesses both loans and emergency grants, as summarized in the chart below.
 - **SBA Paycheck Protection Program:** The CARES Act established a new, \$349 billion Paycheck Protection Program providing for SBA-guaranteed loans made by SBA lenders to eligible recipients. Administered by the SBA through its 7(a) lending program, loan amounts are based on a borrower’s monthly payroll costs, capped at \$10 million per loan, and are forgivable as outlined below. **Note that recipients are likely precluded from receiving funding under both the Paycheck Protection Program and the EIDL program for the same purpose.**
 - **Emergency Relief Funds for Medium Size U.S. Businesses:** The CARES Act also authorized an up to \$500 billion relief program for the U.S. Treasury to make loans, loan guarantees, and other investments in support of eligible businesses, states and municipalities, including special assistance for eligible mid-size businesses (500-10,000 employees). As of early April 2020, more detailed guidance regarding this program, and especially about the “Main Street Lending” program, had not been issued.
- The chart at the link below summarizes information as of April 2, 2020. Application requirements, processes, timing, etc. are pending ongoing rulemaking from the U.S. Treasury and the SBA. The information below is subject to change at any time, as the U.S. Treasury and the SBA continue to issue guidance on how and when to provide access to these programs under the CARES Act
 - <https://www.wsgr.com/images/content/2/4/24862/EIDL-loan-chart.pdf>

Paycheck Protection Program (PPP) Loans

■ Eligibility

- Small business concerns, non-profits and certain other entities and individuals
 - A small business concern has fewer than (a) 500 U.S.-resident employees or (b) a greater number if specified by the SBA for the company’s NAICS code (any specified revenue caps do not apply)
 - “Research and Technology in Biotechnology” must have less than 1,000 employees
 - “Semiconductor and Related Device Manufacturing” must have less than 1,250 employees
 - In determining the number of employees, certain SBA affiliation rules apply
- Employees calculated as average number of individuals employed in the U.S. in the preceding completed 12 calendar months as of the date of application
- “Employees” includes full-time, part-time and other employees, but excludes independent contractors

Eligibility

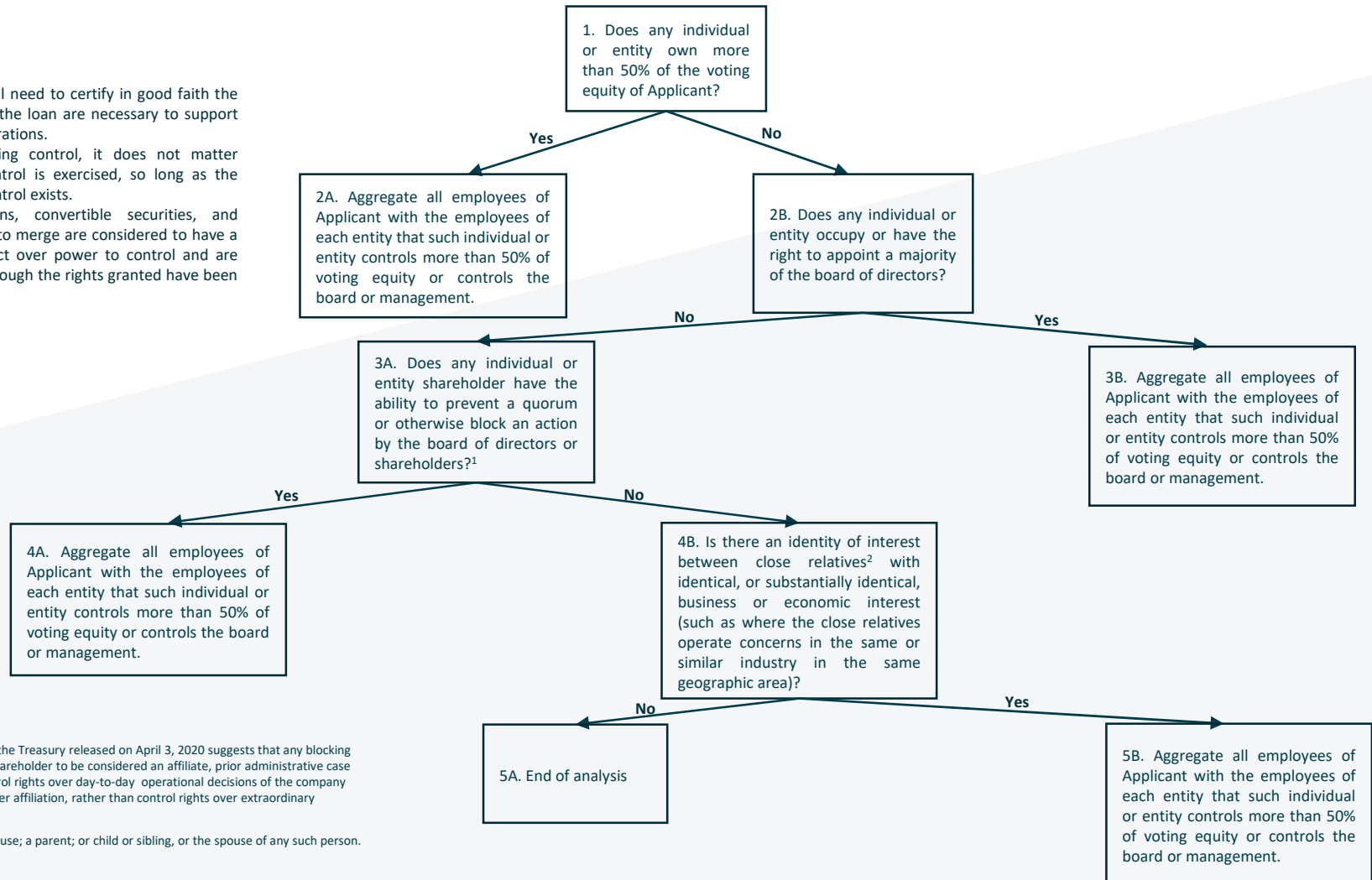
Additional Requirements

- In operation on February 15, 2020 with at least one employee or independent contractor
- Loan proceeds are ***necessary*** to support ongoing operations
- Certify eligibility
 - 20% owners no longer required to also certify eligibility
 - Company still required to certify information regarding 20% owners
 - No default/delinquent SBA/federal loans by owner or any business controlled by owner
 - Addendum listing all businesses under common control
 - Negative representation regarding suspension, disbarment, and criminal violations

Affiliation Analysis

Note:

- Applicant will need to certify in good faith the proceeds of the loan are necessary to support ongoing operations.
- In determining control, it does not matter whether control is exercised, so long as the power to control exists.
- Stock options, convertible securities, and agreements to merge are considered to have a present effect over power to control and are treated as though the rights granted have been exercised.



¹While guidance from the Treasury released on April 3, 2020 suggests that any blocking right will cause such shareholder to be considered an affiliate, prior administrative case law suggests that control rights over day-to-day operational decisions of the company are more likely to trigger affiliation, rather than control rights over extraordinary decisions.

²Close Relative is a spouse; a parent; or child or sibling, or the spouse of any such person.

PPP Loans for Foreign-owned Applicants

Additional Considerations

- **Additional eligibility requirements for (1) wholly-owned U.S. subsidiaries of non-U.S. companies and (2) other U.S. companies that are not at least 51% owned by, and for which the management and daily operations of the business are not controlled by, individuals who are U.S. citizens and/or who have Lawful Permanent Resident (i.e., “Green Card”) status**
 - The subsidiary must be located in, operate primarily within, and pay taxes to, the United States
 - Loan proceeds may be used exclusively for the benefit of U.S. operations
 - Separate continual and consistent management of the business has been provided by a U.S. citizen or by a verified Lawful Permanent Resident (i.e., a “Green Card” holder) and will continue indefinitely
 - Management has operated the business for at least one year prior to the loan application date

- **The CARES Act appears to have eliminated for PPP loans the personal guaranty and collateral requirements required of foreign-owned applicants for analogous SBA loans**

- **Under the affiliation rules, wholly-owned U.S. subsidiaries of UK, European and other non-U.S. parent companies will need to affiliate with that parent company and the parent company’s other controlled entities**
 - The affiliation analysis on the prior slide will be relevant for VC/PE-backed non-U.S. parent companies of U.S. subsidiaries considering PPP loans
 - [SBA Guidance on the Affiliation Rules applicable to the Paycheck Protection Program](#)
 - [The CARES Act: SBA Size and Affiliation Issues for Loan Programs](#), Wilson Sonsini
 - [Affiliation in the Context of SBA Loans – Guidance for VC Investors](#), National Venture Capital Association (NVCA)
 - [PPP Loan Program: Application and Affiliation Guidance](#), NVCA

CARES Act

Additional Loan Assistance Resources

- [SBA Borrower Application Form for Paycheck Protection Program](#)
- [U.S. Treasury Department Paycheck Protection Program Information Sheet](#)
- [SBA Paycheck Protection Program Frequently Asked Questions](#)
- [SBA List of the Most Active 7\(a\) Lenders](#)
- [The CARES Act: A Summary of Loan Programs](#), Wilson Sonsini
- [Coronavirus Emergency Loans - Guide and Checklist for Small Businesses and Nonprofits](#), US Chamber of Commerce
- [Main Street Lending Program Announced](#), Wilson Sonsini

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The CARES Act: A Summary of Loan Programs

ALERTS
March 30, 2020

On March 27, 2020, the President signed the CARES Act, a \$2 trillion stimulus package.

The CARES Act expands or establishes the new SBA Paycheck Protection expansion of the Small Business Administration program.

SBA Size of Business Eligibility

Venture capital and other investor-backed companies and companies that know at this point whether the SBA action would be required. For some size qualifications for an SBA loan program, portfolio companies of one or more employees, a company could be required to meet the SBA's size rules. Making a determination under the CARES Act is challenging for companies. For more information regarding the CARES Act.

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The CARES Act: SBA Size of Loan Programs

ALERTS
March 30, 2020

On March 27, 2020, the President signed the CARES Act, a \$2 trillion stimulus package.

The CARES Act expands or establishes multiple loan programs, both administered by the U.S. Small Business Administration. The rules, however, might make it challenging for companies to take advantage of these programs.

This alert provides an overview of the SBA's size of business eligibility.

Size Matters When Determining Eligibility

In order to be eligible for the PPP loans and EIDL, a company must meet the SBA's existing "small business" size standards.

The size qualification for a "small business" is based on the number of employees (including all full-time, part-time, and seasonal employees) or the number of employees, or some other qualification, for a company. For more information regarding the CARES Act, see this linked table. For example, companies in the construction industry must have less than 500 employees, and companies in the manufacturing industry must have less than 1,000 employees, or

Prepared by the U.S. CHAMBER OF COMMERCE

CORONAVIRUS EMERGENCY LOANS Guide and Checklist for Small Businesses and Nonprofits



The Coronavirus Aid, Relief, and Economic Security (CARES) Act allocated \$350 billion to help small businesses and nonprofits keep workers employed amid the pandemic and economic downturn. Known as the Paycheck Protection Program, the initiative provides 100% federally guaranteed loans to eligible organizations.

Importantly, these loans may be forgiven if borrowers maintain their payroll during the crisis or restore their payroll afterward.

The administration soon will release more details including the list of lenders offering loans under the program. In the meantime, the U.S. Chamber of Commerce has issued this guide to help organizations understand what to expect and prepare to file for a loan.

Here are the questions you may be asking—and what you need to know.

4. Tax Relief

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Tax Relief

Recent and pending legislation regarding tax benefits

- On March 18, 2020, the “Families First Coronavirus Response Act” was signed into law, making emergency supplemental appropriations to address the COVID-19 emergency and enact payroll tax credits for certain smaller businesses. Since these tax credits apply to payroll, not income, tax, a wide range of businesses are expected to benefit. Employers may retain certain payroll tax deposits in the amount of the tax credits, and the IRS will implement expedited refund procedures. The new payroll tax credits include credits for paid sick leave and paid family leave. For additional information, see the full Wilson Sonsini alert [here](#).

- On March 20, 2020, the IRS outlined certain relief from tax deadlines to Americans and their businesses adversely affected by the COVID-19 emergency. Notably, tax filing and payment deadlines have been postponed until July 15, 2020 and there is no cap on the amount of tax that any taxpayer may postpone. Note that this change only applies to U.S. federal income tax filings and payments, as deadlines for filing any other U.S. federal tax or information remains unchanged. For additional information, see the full Wilson Sonsini alert [here](#).

- The CARES Act provides additional tax relief to businesses, as outlined below.

- The CARES Act contains several key measures intended to provide expedited tax relief to business and individual taxpayers.
 - First, the CARES Act establishes a new refundable tax credit for businesses that retain employees during the COVID-19 crisis. This credit is in addition to the new refundable payroll tax credits for businesses for the cost of paid sick leave and paid family leave enacted earlier this month and described in this [Client Alert](#). Since these tax credits apply to payroll, not income, tax, a wide range of businesses (including businesses that are not expected to pay income taxes in 2020) are expected to benefit. In addition, the CARES Act allows most employers to defer certain 2020 payroll taxes until 2021 and 2022.
 - Second, the CARES Act makes several U.S. federal income tax changes intended to benefit businesses navigating the COVID-19 crisis, including increasing interest deduction allowances and temporarily relaxing certain limitations on the use and carryback of net operating losses (NOLs).

Tax Relief

Recent and pending legislation regarding tax benefits

Payroll Tax Measures

- **Employee Retention Credit (Section 2301)**—The CARES Act establishes a new refundable tax credit against the 6.2 percent Social Security payroll tax (Old-Age, Survivor, and Disability Insurance (OASDI) tax) imposed on employers by Section 3111(a) of the U.S. Internal Revenue Code of 1986, as amended (the Code) to assist employers that retain employees through the COVID-19 crisis. The amount of the credit is 50 percent of "qualifying wages" paid to an employee after March 12, 2020 and before January 1, 2021 and is capped at \$10,000 of qualifying wages per employee (giving a maximum credit of \$5,000 per employee).
 - *Triggering conditions*—The credit is available to employers engaged in a trade or business that i) are subject to closure due to COVID-19 orders or ii) experience a "significant decline" in gross receipts. "Closure" means a full or partial suspension of business activity due to orders from an appropriate governmental authority due to COVID-19. A "significant decline" in gross receipts occurs during the period beginning with the first calendar quarter beginning after December 31, 2019 in which the employer's gross receipts drop to less than 50 percent of gross receipts for the same quarter in the prior year and ending with the first quarter in which gross receipts are greater than 80 percent of gross receipts for the same calendar quarter in the prior year.
 - *Application based on number of employees*—Small employers (with 100 or fewer employees) are eligible for the credit for any wages paid during a closure or a period of significant decline in gross receipts. Larger employers (with more than 100 employees) are eligible for the credit only for wages paid with respect to employees who are not providing services due to closure or a significant decline in gross receipts.
 - *No overlap with other tax credits*—Qualifying wages do not include wages taken into account for the new employer tax credits for COVID-19-related paid sick leave and paid family leave enacted earlier this month or the existing credit for paid family and medical leave under Section 45S of the Code, but do include certain expenses incurred by the employer to maintain a group health plan that are allocable to the wages.
 - *SBA Loan recipients ineligible*—Any employer that receives a PPP Loan as described in this [Client Alert](#) is not eligible for the credit.
- **Payroll Tax Deferral (Section 2302)**—Employers may defer deposit and payment of the 6.2 percent Social Security payroll tax for the remainder of 2020 beginning with the date of enactment of the CARES Act. Fifty percent of the tax deposits may be deferred until December 31, 2021, and the remaining 50 percent may be deferred until December 31, 2022. The deferral does not apply to the employee portion of payroll taxes or the Medicare tax imposed on employers. Employers are not eligible for the deferral if they have PPP Loans forgiven, as described in this [Client Alert](#), (including comparable loans provided by newly participating financial institutions under the CARES Act).

Tax Relief

Recent and pending legislation regarding tax benefits

■ Net Operating Loss Provisions (Section 2303)

- Key changes to the rules for using corporate NOLs are summarized below. This [Client Alert](#) explains the changes to the NOL rules in greater detail.
 - **Suspension of 80 Percent Limitation**—Under current Section 172 of the Code, a taxpayer's NOL deduction with respect to NOLs arising in taxable years beginning after December 31, 2017 (NOLs arising post-2017) is limited to no more than 80 percent of the taxpayer's taxable income (the 80 Percent Limitation). The CARES Act suspends the 80 Percent Limitation for taxable years beginning before January 1, 2021. For calendar year taxpayers, this means that NOLs carried forward or back to taxable years 2018, 2019, or 2020 could offset up to 100 percent of the taxpayer's taxable income in such year.
 - **5-Year Carryback of Certain NOLs**—Under current law, NOLs arising post-2017 generally cannot be carried back. The CARES Act generally allows a five-year carryback (the 5-Year Carryback) for NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 (taxable years 2018, 2019, and 2020, for a calendar year taxpayer).
 - **Other Amendments**—The CARES Act contains a number of amendments to the NOL provisions, including provisions that address the overlap of the Section 965 "transition tax" and the new 5-Year Carryback and clarify the application of the 80 Percent Limitation when both NOLs arising post-2017 and other NOLs are carried to the same year.

■ Other Business Tax Measures

- *Acceleration of Credit for Corporate AMT (Section 2305)*
 - Under current Section 53 of the Code, corporate taxpayers are allowed a refundable credit in respect of alternative minimum tax (AMT) that was paid before the repeal of the corporate AMT by the Tax Cuts and Jobs Act (and not previously credited). The credit could be claimed over a four-year period ending with the corporation's taxable year beginning in 2021. The CARES Act accelerates the refundable credit so that the credit can be claimed in full by the first tax year beginning in 2019. In addition, a corporate taxpayer may elect to accelerate the entire credit to the corporation's taxable year beginning in 2018. In that case, the procedures applicable to tentative carryback adjustments (so-called "quickie refunds") apply for purposes of seeking a refund for the credit. For further information, see this [Client Alert](#).

Tax Relief

Recent and pending legislation regarding tax benefits

- *Business Interest Limitation (Section 2306)*

- **Increase of 30 Percent Limitation to 50 Percent**—Under current Section 163(j) of the Code, a taxpayer is generally permitted to deduct business interest paid or accrued only to the extent of business interest income, plus 30 percent of "adjusted taxable income." The CARES Act increases the limitation from 30 percent to 50 percent of adjusted taxable income for taxable years beginning in 2019 or 2020, except the 50 percent limitation applies only for taxable years beginning in 2020 for entities taxed as partnerships for U.S. tax purposes. Additionally, a partner is allowed to deduct in its first taxable year beginning in 2020 (without regard to the adjusted taxable income limitation) 50 percent of the partner's share of the excess business interest for any taxable year of a partnership beginning in 2019 (with the balance subject to the normal rules, as amended by the CARES Act). Taxpayers are permitted to elect out of some of these rules.
- **Election to Use 2019 Adjusted Taxable Income**—The CARES Act further allows a taxpayer to calculate the limitation for a taxable year beginning in 2020 based on its adjusted taxable income for its last taxable year beginning in 2019.
- For further information, see this [Client Alert](#).

- *SBA Loan Forgiveness Income Exclusion (Section 1106)*

- As described in this [Client Alert](#), an SBA PPP Loan recipient is eligible for forgiveness on an SBA loan in an amount equal to certain payroll and other expenses. For tax purposes, loan forgiveness generally results in income from discharge of indebtedness that is in includible in a taxpayer's gross income unless a specific exclusion applies. The CARES Act provides a new exclusion from gross income for discharge of indebtedness income arising from qualifying forgiveness of an SBA PPP loan.

5. Contracts and Transactions

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Contracts and Transactional Matters

Force Majeure Clauses

- The uncertainty given the spread of COVID-19 extends to existing contractual relationships, and one question which may arise is whether this unprecedented disruption excuse delays or non-performance under a contractual force majeure clause. The answer will turn on, among other factors, the following three factors.
 - Purpose & Triggering Terms: Many clauses set out specific triggering events, which tend to vary by contract. The following triggering events, if listed, may be implicated by COVID-19 and current events: epidemic / pandemic / viral or communicable disease outbreak, quarantines, lack of or inability to obtain fuel, power, components, or materials, disruption of supply chains, disruption of transportation systems, disruption of labor force, national emergency, act, order, or requirement of any governmental authority, "Act of God", or a "catch-all" phrase such as "or other similar causes beyond the control of such party".
 - Jurisdictional Differences: While courts in different jurisdictions generally consider the same factors in their analysis, they apply these factors differently, often in ways that can prove case-dispositive.
 - COVID-19 and Fact Specific Issues: In evaluating the impact of COVID-19 on existing contractual relationships, it is important to evaluate the triggering event impacting performance, whether the triggering event is encompassed by the language of the clause, governing law, foreseeability, affect on performance and whether performance is still possible or impracticable, steps to mitigate, remedies provided by the force majeure clause or otherwise under the contract and steps required to exercise rights under the contract.
- Successful invocation of a force majeure clause is a fact specific analysis. Moreover, as events change and continue to unfold, businesses should closely monitor how shifting dynamics may implicate the express triggering events listed and the effect on performance. Many businesses will no doubt find themselves on both sides of this issue, as both promisor and promisee, depending on the circumstances and context. We advise businesses to keep these factors in mind when entering into new contracts for which there is a risk of COVID-19 impacting future performance.
- For additional information, see the Wilson Sonsini COVID-19 Force Majeure alert [here](#).

Contracts and Transactional Matters

Breach Related to Compliance with Law Representations and Warranties

- Given the changing and rapidly evolving legal landscape, heightened attention should be given to representations and warranties made, or in the process of being negotiated, in which the company reps that it is in compliance with all applicable laws and regulations.
- The following areas of law are examples that may be implicated by COVID-19 and the related orders put in place to combat the virus:
 - Employment and Labor
 - Privacy and Information Security
 - Employee Benefits and Executive Compensation
 - Antitrust & International Trade
 - Tax laws and regulations
 - SEC Disclosure, Securities Laws and other corporate governance measures
 - FDA regulations and guidelines
- Representations should be reviewed and proactively managed to ensure compliance and prevent breaches.
- Consider any necessary amendments to existing agreements, as well as additional disclosures and carve-outs relating to any impact, existing or potential, arising from the COVID-19 pandemic.

6. Debt & Credit Considerations

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Debt and Credit Considerations

Companies with Existing Loan Facilities

- In times like these, cash is king, and a company's debt financing is critical to managing cash flows.
- Borrowers can proactively review terms in their existing debt facilities for ways to reduce pressure on company cash flows and to identify possible amendments, postponements or waivers, even if only temporary and in the near term:
 - Principal and interest payment dates and amounts
 - Interest rates, if based on financial ratios
 - Consider using PIK (paid in kind) interest, though the cost of PIK interest should be weighed carefully
 - Prepayment triggers and premiums
 - Financial covenants, if any
 - Excess cash flow sweeps, if any
 - Conditions to drawing down additional funds
 - Other covenants that may require more time in order for a company to comply
 - Milestone dates and conditions

Debt and Credit Considerations

Companies with Existing Loan Facilities (continued)

- Borrowers should proactively review Events of Default and covenant triggers in their existing debt facilities to take stock of potential upcoming default and compliance risks and timing:
 - Reporting or other time deadlines that the Company may miss due to audit delays, supply chain disruptions, regulatory changes, and the Covid-19 situation generally
 - “Bright line” triggers such as payment defaults or financial covenant breaches
 - Other covenant compliance risks
 - Mandatory prepayment triggers and premiums
 - Especially for biotech companies -- Milestone dates and conditions which may be delayed due to regulatory authority (FDA, etc) or other delays
 - Biotech companies whose businesses are ***not*** related to Covid-19 or related essential businesses may experience regulatory or other delays, as priority is given to Covid-19 or related essential businesses.

- Consider possible amendments, postponements, waivers and forbearances to proactively reduce or mitigate near-term default risks

Debt and Credit Considerations

Companies with Existing Loan Facilities (continued)

If the Company Has:

- Unused credit available, or the capacity to ask its lender to increase available credit
- Any deadlines, such as reporting covenants, delivery of financial statements, payment dates, milestones, dates by which credit availability ends, etc.

Consider:

- Whether to draw down additional loan(s) or to approach the lender to increase available credit
 - Are there any Material Adverse Effect, Material Adverse Change, or Investor Support conditions, and if so, can they be met?
 - Whether representations and warranties would be materially true and correct at the time of such drawdown?
 - Financial covenant and other financial effects
- Amending deadline dates, such as:
 - Date by which any upcoming financial statements are due, as most auditors will be delayed generally
 - Interest payment dates – pushing out and/or consider using paid-in-kind interest (vs. cash pay interest) for the next few months, to help conserve cash in the near term; however, cost of PIK interest should be carefully evaluated

Debt and Credit Considerations

New Loan Facilities in the time of COVID-19

Key Terms To Review:

- All drawdown and credit availability conditions and dates
- All payment terms and timing
- Interest provisions – payment dates, cash vs. PIK interest, if tied to any financial covenants
- Any mandatory prepayment terms
- Any other deadlines, such as reporting covenants, delivery of financial statements, milestones, etc.
- Any financial covenants, and any other terms tied to a financial ratio or measure
- Operational covenants in light of the Covid-19 situation
- Events of Default – ability to cure

Consider:

- Are there any Material Adverse Effect, Material Adverse Change, or Investor Support conditions, and if so, can they be met?
- Effects on any financial or liquidity covenants
- Other terms which may be tied to financial measures or ratios (such as pricing, excess cash flow sweeps, reserve accounts, etc.)
- Adding sufficient flexibility to representations and warranties that must be true and correct at the time of closing and funding
- Negotiating sufficient operational flexibility in the covenants
- Ways to mitigate default risk by lengthening cure periods, adding opportunities to cure, materiality qualifications, etc.

Debt and Credit Considerations

Your Company May Also Be a Creditor: Supplier, Customer and Counterparty Risk

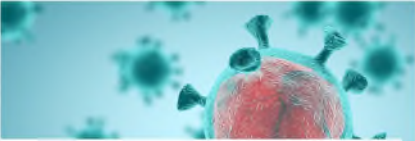
- A company may also be (or become) a creditor, if suppliers, vendors, customers and other counterparties start having their own cash flow difficulties and do not (or cannot) pay the company on time
 - Monitor and identify credit risks
 - UCC and lien searches are a quick and easy way to see if a counterparty has secured creditors in the U.S.
 - In some cases, a company may be able to use purchase money liens to improve its position
 - In some cases, a company may wish to consider asking for some kind of credit and/or guaranty support, or some kind of security, from a counterparty

Debt and Credit Considerations

Additional Resources

- [Venture Lending in a Time of Crisis](#), Wilson Sonsini
- [Considerations in Accessing Revolving Credit Lines](#), Wilson Sonsini

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Considerations in Accessing Revolving Credit Lines

ALERTS
March 24, 2020

The COVID-19 pandemic has resulted in unprecedented economic challenges for numerous industries throughout the world that have put tremendous stress on the global financial markets. As a result, numerous companies have been considering ways to manage their liquidity as they manage the adverse impacts of the COVID-19 pandemic on their business. Companies with revolving credit lines have been drawing down their revolving capacity and their financial investors have been encouraging this utilization of their revolving credit lines to enhance their liquidity position.

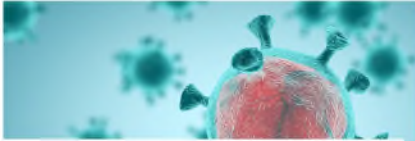
When accessing revolving credit lines, companies should carefully consider the funding conditions required by the terms of their specific facility. Typically, there are two primary funding conditions in most revolving credit lines.

Representations and Warranties – a company must bring down the representations and warranties in their revolving credit lines, the most salient of which is a representation that there has been no material adverse effect (MAE) on the business, property, operations, or financial condition of the company. In the middle market and/or in the venture technology lending markets, there may also be a specific condition whereby the borrower is required to certify as to the absence of an MAE.

No Default or Event of Default – a company must certify that there is no default or event of default existing at the time of request of the borrowing.

The analysis of whether an MAE has occurred is highly fact-specific and the relevant case law has not established any bright-line tests or quantitative rule of thumb that can be relied upon to assert the presence

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Venture Lending in a Time of Crisis

ALERTS
March 24, 2020

Many early stage and emerging growth companies utilize venture lending as a source of funding to compliment equity financing. But what happens to these loans in difficult and uncertain times? Wilson Sonsini has experience in the venture lending markets that goes back more than three decades through multiple economic cycles and we know the active participants in the market well. We have helped both borrowers and lenders through difficult transactions in similar circumstances and we can offer some thoughts on the current situation.

Not All Lenders Are Created Equal

Some of the venture banks and non-bank lenders have weathered multiple downturns calmly and thoughtfully and continued to provide credit, taking a long-term view. The venture banks are generally smaller to mid-sized banks and generally did not have the liquidity issues in 2008-2009 that some of the larger money center banks had. Venture lending has been central to their business and most, but not all, did not deviate from their path because of shorter term circumstances. Borrowers have had more varied experiences with the non-bank lenders. Some proved similarly steady during downturns and have had dedicated sources of funding that are less affected by broad financial market problems. In contrast, some non-bank lenders had their funding sources dry up, which caused them to stop lending or even try to call in their loans when they had an opportunity. While it is clear that the Federal Reserve and the financial regulators are trying to keep the financial markets liquid, borrowers should keep an eye on the funding sources of their lenders and seek information on how they have behaved in similar circumstances.

Different Types of Loans

7. FDA Actions and Guidance

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FDA Actions and Guidance

Recent FDA Regulatory Policies to Address the COVID-19 Threat

- [CARES Act Contains Significant New Over-The-Counter \(OTC\) Drug Provisions](#): Among other things, the CARES Act provides further incentives to develop OTC drugs, provides fee driven mechanisms to request OTC drug label changes, creates drug repurposing support, and clarifies when an OTC drug is misbranded. The FDA issued a recent statement that calls the CARES Act OTC provisions a "landmark step that will have an impact lasting long after the current public health emergency."
- [Discontinuance and Interruptions in Manufacturing During COVID-19](#): On March 31, 2020, the FDA issued guidance surrounding notification procedures if a manufacturer suffers a permanent discontinuance or interruption in manufacturing under Section 506C of the Federal Food, Drug, and Cosmetic (FD&C) Act. The FDA guidance discusses the requirement for applicants and manufacturers to notify the FDA of a "permanent discontinuance in the manufacture of certain products or an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in the supply of that product in the United States." The official guidance can be located [here](#).
- [FDA Issues Guidance on Use of 3D Printing on Medical Devices, Accessories, Components, and Parts](#): On March 26, 2020, the U.S. Food and Drug Administration (FDA) issued guidance surrounding the use of 3D printing on medical devices, accessories, components, and parts during the COVID-19 pandemic. The official guidance can be located [here](#).
- [FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections](#): On March 18, 2020, the FDA announced that it has temporarily postponed all domestic routine surveillance facility inspections. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed if mission-critical. The FDA is evaluating additional ways to conduct for-cause inspections including, among other things, evaluating records in lieu of conducting an onsite inspection.
- [FDA Issues Guidance for Conducting Clinical Trials](#): On March 18, 2020, the FDA issued a guidance for industry, investigators, and institutional review boards conducting clinical trials during the COVID-19 pandemic. The guidance outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity. Considerations recommended include, among others, sponsors evaluating alternative methods for assessments, like phone contacts or virtual visits and offering additional safety monitoring for those trial participants who may no longer have access to investigational product or the investigational site.

FDA Actions and Guidance

Recent FDA Regulatory Policies to Address the COVID-19 Threat (continued)

- [FDA Issues Temporary Policy for FSMA Onsite Audit Requirements](#): On March 17, 2020, to help prevent disruptions in the food supply-chain during the COVID-19 pandemic, the FDA issued a temporary policy for Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements.
- [FDA Provides More Regulatory Relief During Outbreak, Continues to Help Expedite Availability of Diagnostics](#): On March 16, 2020, the FDA issued a guidance that provides recommendations for test developers who wish to develop serological tests; puts forth a policy for states to take responsibility for tests developed and used by laboratories in their states; and announces enforcement discretion towards commercial manufacturers distributing and labs using new commercially developed tests prior to the FDA granting an emergency use authorization, under certain circumstances.
- [FDA and FTC Warn Seven Companies Selling Fraudulent Products that Claim to Treat or Prevent COVID-19](#): On March 9, 2020, the FDA and the FTC issued warning letters to seven companies for selling fraudulent COVID-19 products. The products were considered unapproved drugs that pose significant risks to patient health and violate federal law. Rather than affording the usual 15 days for company responses, the warning letters requested companies respond in 48 hours describing the specific steps they have taken to correct the violations.
- [Supply Chain Update](#): On February 27, 2020, the FDA announced initiatives to help curb potential disruptions to supply or shortages of medical products in the U.S. Certain manufacturers of medical products have been asked to evaluate their supply chain as communicating potential disruptions can help work with companies to help identify interventions to mitigate potential shortages. The announcement also advocated four specific proposals included in the President's budget that the FDA believes help prevent or mitigate medical product shortages: lengthen expiration dates to mitigate critical human drug shortages, improve critical infrastructure by requiring risk management plans, improve critical infrastructure through improved data sharing and require more accurate supply chain information, and establish reporting requirements for device manufacturers.

8. Patent Filings

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Patent Filings

Strategic Delay: What if you foresee a budget shortfall, and need to act now?

- Prioritize patent families into those that cover your current product, those that may cover a future product, and those that do not cover either category (e.g., terminated programs, design-arounds, etc)

- For those that cover your current product:
 - Take maximum extensions in the less-major markets, usually such costs are much less than putting together a response.

- For inventions covering a future product:
 - Understand the competitive landscape, and make an educated guess if you need to act now, or can wait several months or a year. Perhaps your current filings can give you some protection. Make sure no public disclosures.

- For terminated programs: consider abandoning the patent families.

- For design-arounds: combine maximum extensions and filing continuation/divisionals to push costs down the road.

Patent Filings

Basic USPTO operations currently continue without interruption.

- Patent and trademark application deadlines and other deadlines are not extended. They are not granting any waivers or extensions of dates or requirements set by statute.
- Restoration: The USPTO is waiving petition fees in certain situations for customers impacted by COVID-19. This means if an application goes abandoned because the applicant was unable to timely reply due to the effects of the pandemic, the USPTO will waive the revival petition fee. The petition must be filed no later than two months of the issue date of the notice of abandonment.
- There will be no in-person interviews, but video or telephone interviews remain available. Examiner and examining attorney interviews, Patent Trial and Appeal Board (PTAB) and Trademark Trial and Appeal Board (TTAB) oral hearings, and other similar in-person meetings with parties and stakeholders scheduled to take place at USPTO offices will be conducted remotely by video or telephone.
- See the following link for up to date alerts from the [USPTO](#).

Patent Filings

European Deadline Extensions Available and Patent Office Remains Active

- **Automatic Extension:** The EPO announced that certain deadlines expiring after March 15, 2020 are extended to April 17, 2020. These deadlines include the deadline to respond to search reports, and the deadline to enter the European national stage.
 - The EPO's extension of certain deadlines is not a blanket extension. It excludes deadlines to pay renewal fees, and to file divisional applications (divisional applications must still be filed prior to publication of the grant of a patent).
 - Importantly, the EPO's deadline extension does not create a grace period to file a patent application following a public disclosure.
 - If you were not able to meet a deadline prior to March 15, 2020 because of disruptions due to the COVID-19 pandemic, certain remedies will be available.

- All oral proceedings in examination and opposition proceedings scheduled until April 17, 2020 have been postponed, unless they have already been confirmed to take place by means of videoconferencing.

- If the COVID-19 pandemic continues to disrupt operations at the EPO after April 17, 2020, the EPO may issue further extensions and delays for various deadlines. Consider PACE request to avoid upcoming glut of cases that used extension.

- See the following link for up to date alerts from the [EPO](#).

Patent Filings

Chinese and Japanese Patent Offices

■ China

- Plan to have filings ready at least one or two days ahead of the deadline.
- Similar to the USPTO, the Chinese Patent Office provided that a restoration of right based on this uncontrollable event may be available if a deadline is not met due to the pandemic and the applicant can provide evidences such as local government declaration or announces of emergency rules, evidences showing the applicant being quarantined, or diagnosis of infection. It is unclear whether/how this applies to applicants outside China, but it may be helpful to keep it in mind as a last resort.
- When interviews are needed, there might be a chance the examiner may not be reachable. There are some uncertainties when needing to schedule phone interviews with the examiners, particularly based on which division and location of the Chinese Patent Office the examiner works. Many examiners are working from home and there are chances of unavailability due to telecommunication issues.
- See the following link for up to date alerts from the [CNIPA](#).

■ Japan

- The Japanese Patent Office is open and functioning normally.
- No extensions of time or special provisions are currently provided.
- Generally, plan to send filings several weeks in advance to allow for translation delays.

9. Patent Post-Grant Proceedings

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Patent Post-Grant Proceedings

Proceedings Continue Despite COVID-19 Disruptions

- As of March 26, 2020, the Patent Trial and Appeal Board (PTAB) and the United States Court of Appeals for the Federal Circuit (CAFC) have made adjustments in their practices to accommodate the new realities of COVID-19 and social distancing, but remain open for business.
 - Parties before either body should continue to meet set deadlines. Importantly, United States Patent and Trademark Office (USPTO) has stressed that it [cannot waive statutory deadlines](#).
- Adjustments at the PTAB
 - The USPTO has closed its physical offices to the public, including PTAB hearing rooms, until further notice but is otherwise continuing its operations.
 - The PTAB will provide parties with notice in each affected case regarding options for video or telephonic hearings.
 - Thus far the PTAB has not needed to exercise its ability to extend cases solely due to COVID-19 related issues. We have seen evidence that the PTAB is more liberally employing other extension mechanisms, such as extensions in joinder cases.
- Adjustments for Parties at the PTAB
 - While much of the work parties do during the course of a PTAB trial can occur remotely, depositions pose a particular challenge.
 - Travel for client, co-counsel, and witness meetings is restricted.
 - When actual papers are served (typically just the petition and accompanying exhibits), parties should consider providing courtesy copies by email when possible to reduce COVID-19 related excuses, such as delay in receiving service.
- Adjustments at the CAFC
 - The CAFC, which historically has been generous in granting oral argument, will be more selective in the cases it hears and will decide more cases solely on the briefs.
 - All arguments scheduled for April will be conducted by telephone; no in-person hearings will be held. The parties in scheduled cases will receive updated notices in their cases.
 - Filing of paper copies (now required once briefing has been completed) is suspended until further notice unless the initial filing can only be made in paper.
 - Call volume has forced the CAFC to curtail telephone assistance from the Clerk's Office; questions should be directed to one of two email addresses for case-specific and general questions, respectively.

10. General COVID-19 Resources

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General COVID-19 Resources

- Wilson Sonsini [COVID-19 Client Advisory Resource](#)
- [Crowdsourced database of COVID-19 resources, guidance, and information for startups and entrepreneurs](#), from JetBlue Technology Ventures
- U.S. National Venture Capital Association [COVID-19 Resource for Startups and VCs](#)
- [U.S. Expansion and Fundraising during COVID-19, Mayor's International Business Programme \(London\)](#)



11. General Fundraising Resources

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General Fundraising Resources

- [COVID-19's Influence on the US VC Market](#), Pitchbook
- [COVID-19 European Investor Status List](#), created by Philip Wilkinson
 - A public, open-source spreadsheet with input from UK and other European VCs, Angels, Accelerators and Family Offices who are investing amid COVID-19
- [Uncapped](#), revenue-based finance provider for UK/European emerging companies
- [Venture Financing Term Sheet Generator](#), Wilson Sonsini
- [Convertible Note Term Sheet Generator](#), Wilson Sonsini
- [U.S. Expansion and Fundraising Library](#), Tech Nation and Wilson Sonsini



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