

U.S. CARES Act Supply Shortage Provisions: What Drug and Device Manufacturers Need to Know



On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public discussion and concern over the availability and accessibility of critical medical devices, such as ventilators, and the pandemic has highlighted gaps in the U.S. Food and Drug Administration's (FDA's) authorities regarding medical product shortages. FDA has been able to collect information on drug shortages and take steps to help prevent or mitigate such shortages under authorities set forth in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). However, FDA had not, until now, had equivalent authority with regard to shortages of critical devices. Among the many provisions of the CARES Act ("the Act") are amendments and additions to the Federal Food, Drug, and Cosmetic Act (FDCA) that give FDA the ability to effectively address such shortages. Additionally, the Act enhances FDA's existing authority with respect to drug shortage measures. Below, we have highlighted the key provisions in these areas under the new law.

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CMS Expands Availability of Advances on Medicare Reimbursement; U.S. CARES Act Increases Medicare Reimbursement Rates



In response to the COVID-19 public health emergency, the Centers for Medicare & Medicaid Services (CMS) announced on Saturday March 28, 2020, that it is expanding its Medicare Accelerated and Advance Payment Program (AAPP) to allow nearly all

Medicare providers and suppliers to receive advances on future Medicare reimbursement. To provide further relief to healthcare providers and suppliers, the Coronavirus Aid, Relief, and Economic Security U.S. Cares Act (CARES Act), which was signed into law on March 27, 2020, eliminates from May 1, 2020, through December 31, 2020 the 2% sequestration-mandated reductions to Medicare reimbursement. We review these developments in greater detail below.

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Collaboration, License and other Commercial Agreements: Key Considerations for Life Sciences Companies in the Age of COVID-19



The COVID-19 pandemic is continuing to cause major global disruption to the activities of development stage and other life sciences companies due to, among other factors, limited or no access to clinical trial sites, reduced supply levels for active pharmaceutical ingredients or other key materials needed to make drug candidates or medical devices, and the inability of personnel to access laboratory and other specialized work spaces.

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Labor Cost Reduction Options for Employers in a Distressed Economy: The CARES Act and Other Considerations



The Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), which was enacted on March 27, 2020, created new programs and expanded existing programs in ways that significantly affect the options for employers. This alert identifies key aspects of the CARES Act that can affect employers’ decisions in managing payroll costs during this challenging period. This alert also reviews other considerations for employers, including federal and state plant closing laws and Fair Labor Standards Act (“FLSA”) requirements. This alert focuses on considerations based on federal law and the laws of California, Massachusetts and New York.

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[Update: How Life Sciences Companies Can Assess Stay-At-Home Restrictions in MA and CT](#)



Over the past week, the governors of several states have issued “stay-at-home” orders to combat the spread of the coronavirus known as COVID-19. These stay-at-home orders significantly limit freedom of movement within the affected states and instruct businesses to institute remote work solutions for their employees—or else to shut their doors entirely.

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[COVID-19: Business Interruption and](#)

[Insurance Amid a Pandemic](#)



Businesses in the United States and around the world are undergoing a fundamental and unprecedented disruption as a result of the coronavirus pandemic (COVID-19). State governments have issued “shelter-in-place” and “stay-at-home” orders to the general population, postponed or otherwise cancelled schools in full, and shut down all businesses except those deemed “essential” or “critical” to the maintenance of our country. These actions have already caused dramatic losses of income to business, and those losses will continue to grow as the actions necessary to combat the coronavirus continue to take hold. Fortunately, businesses may have an avenue available to them to recoup some or all of these losses through business interruption coverage in commercial property insurance.

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[The Implications of Coronavirus \(COVID-19\) On Contractual Performance and Negotiations](#)



We encourage our clients to be proactive in responding to the potential impact of COVID-19 on both existing and potential business agreements and relationships. Now that the World Health Organization has formally classified the outbreak of COVID-19 as a pandemic, and the full spread of the virus remains uncertain, it is important that businesses consider the potential implications of the virus on negotiation and performance of their contracts. Whether you are planning to negotiate or currently negotiating contractual agreements, or whether your commercial operations and relationships have already felt the impact of this novel coronavirus, there are several considerations to keep in mind to ensure the smooth operation of your business and to mitigate the potential for litigation amid a pandemic. This alert discusses those considerations.

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