

# **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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