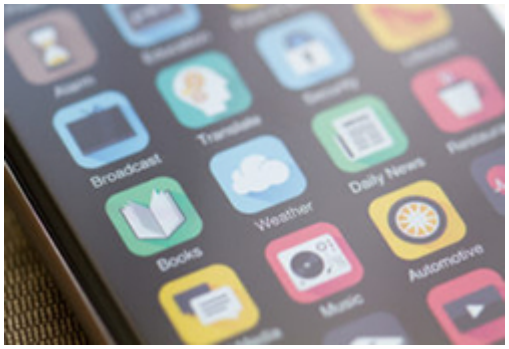
FDA's COVID-19 Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders



Developers of certain digital health devices for treating psychiatric disorders may be able to take advantage of an FDA **enforcement policy**, which remains in effect for the duration of the COVID-19 public health emergency. The policy applies to certain prescription computerized behavioral therapy (CBT) devices for psychiatric disorders, digital health therapeutic devices for psychiatric disorders that operate using a different fundamental technology than CBT, other variations of CBT devices, such as non-prescription devices, and low-risk general wellness and digital health products for mental health or psychiatric conditions.

Relevant psychiatric conditions include Obsessive Compulsive Disorder, Generalized Anxiety Disorder, Insomnia Disorder, Major Depressive Disorder, Substance Use Disorder, Post-traumatic Stress Disorder, Autism Spectrum Disorder, and Attention Deficit Hyperactivity Disorder. The enforcement policy's goal is "to help expand the availability" of these devices to aid those with these conditions "while reducing user and healthcare provider contact and potential exposure to COVID-19."

Under this policy, these devices may be distributed and used without complying with the following regulatory requirements, where such devices do not create an undue risk in light of the public health emergency: 510(k) submission, correction and removal reports, registration and listing requirements, and Unique Device Identification requirements. For those software products with low-risk general wellness indications or functionality, FDA does not intend to enforce regulatory requirements consistent with the agency's existing policies, which were in effect prior to the pandemic. Finally, FDA's enforcement policy sets forth certain recommendations regarding the performance and labeling elements for these devices, such as user instructions that direct the patient to contact a physician before using the device. This enforcement policy highlights FDA's regulatory flexibility for software and app developers in this therapeutic area during the COVID-19 pandemic.

Qualifying for Immunity Under the U.S. PREP Act During COVID-19

 As part of the U.S. government's response to the COVID-19 pandemic, on March 10, 2020, the Secretary of Health and Human Services ("Secretary") issued a Declaration pursuant to the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. § 247d-6d. This Declaration activated immunity from personal injury, property damage, and other types of claims for companies and certain professionals who manufacture, distribute, or use "covered countermeasures"— certain drugs and devices, or components thereof, that may be used to treat COVID-19 patients or combat the COVID-19 pandemic.[1] The PREP Act provides broad immunity from liability, but applies only to products and persons that qualify for the immunity under the PREP Act and the limits established in the Secretary's Declaration.

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Update: U.S. Health and Human Services Clarifies Broad Eligibility of Providers for Payments Under $30 Billion CARES Act Healthcare Provider Relief Fund

 As discussed in Goodwin's prior Client Alert, on April 10, 2020, the U.S. Department of Health and Human Services (HHS) began disbursing $30 billion to Medicare providers and suppliers under the Public Health and Social Services Emergency Fund (PHSS Emergency Fund). HHS is requiring providers to agree to certain terms and conditions or return the payments. A number of the terms and conditions created some confusion as to whether providers who have not provided services directly related to COVID-19 may keep the payments. HHS has now clarified that providers may keep payments distributed under the PHSS Emergency Fund regardless of whether they have or will provide services directly related to COVID-19.

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U.S. Health and Human Services to Begin Disbursing $30 Billion of CARES Act Healthcare Provider Relief Fund

On Friday, April 10, 2020, the U.S. Department of Health and Human Services (HHS) announced it will begin disbursing $30 billion of the $100 billion of the Public Health and Social Services Emergency Fund recently allocated by the Coronavirus Aid, Relief, and Economics Security Act (CARES Act), signed March 27, 2020. Inclusive of the $30 billion, the $100 billion funding will be used to reimburse healthcare providers and facilities.

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U.S. CARES Act Enables Long-Awaited OTC Drug Regulatory Modernization: Key Highlights

Subtitle F of the recently enacted U.S. CARES Act substantially reforms the regulatory framework for non-prescription drugs, representing the most significant update of the review process for over-the-counter (OTC) drugs since that process was first established in 1972. The Act draws from recent legislative proposals to reform OTC regulation, incorporating a modified version of the "Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019" (S. 2740, H.R. 3443) that was passed 91-2 by the U.S. Senate in December 2019. At that time, Senate Health Committee Chairman Lamar Alexander (R-Tenn.) described the legislation as "the most important new law affecting the safety, innovation, and affordability of over-the-counter drugs since the 1970s."

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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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COVID-19: U.S., State Governments Expand Access to Telehealth Services; Reduce Other Barriers to Care


In response to the COVID-19 pandemic, the U.S. and many state governments have taken a number of steps to expand access to telehealth services and reduce other barriers to care. Among other things, the U.S. Centers for Medicare and Medicaid Services (CMS) has eliminated a number of restrictions on the coverage of telehealth services under Medicare to enable coverage of services provided to patients, including new patients, located in their homes. Many commercial payors have also taken action to expand access to telehealth, including by eliminating co-payments for such services. Many states have temporarily waived in-state licensure requirements to enable physicians, registered nurses, licensed practical nurses, nurse practitioners, and other medical personnel licensed in any state to provide telehealth services to their residents. The Department of Health and Human Services (HHS), Office of Inspector General (OIG) announced that physicians and other practitioners will not be subject to

administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services. The HHS Office for Civil Rights (OCR) additionally announced that during the pandemic, it will allow healthcare providers to provide telehealth services to patients through any non-public facing communication applications such as Apple FaceTime, Facebook Messenger, Google Hangout, and Skype. Finally, the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) have both taken steps in response to the COVID-19 pandemic to remove barriers restricting patient access to controlled substances and medicines. We review these developments below.

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