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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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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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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